IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WYETH,	)
Plaintiff,	)
v.	) Civil Action No.: 06-222 JJF
IMPAX LABORATORIES, INC.,	)
Defendant.	)

REPLY DECLARATION OF MARY B. MATTERER IN SUPPORT OF IMPAX'S MOTION TO MODIFY SCHEDULING ORDER

M. PATRICIA THAYER (*pro hac vice*)
JOHN M. BENASSI (*pro hac vice*)
JESSICA R. WOLFF (*pro hac vice*)
DANIEL N. KASSABIAN (*pro hac vice*)
SAMUEL F. ERNST (*pro hac vice*)
HELLER EHRMAN LLP
4350 La Jolla Village Drive, 7th Floor
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Telephone: (858) 450-8400
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RICHARD K. HERRMANN (I.D. No. 405)
MARY B. MATTERER (I.D. No. 2696)
MORRIS JAMES HITCHENS & WILLIAMS LLP
222 Delaware Ave., 10th Floor
Wilmington, DE 19801
Telephone: (302) 888-6800
mmatterer@morrisjames.com

Attorneys for Defendant IMPAX LABORATORIES, Inc.

August 31, 2006

I, Mary B. Matterer, declare:

1. I am a partner at the law firm of Morris, James, Hitchens & Williams LLP, counsel to Defendant Impax Laboratories, Inc. ("Impax") in this matter.

2. Attached hereto as Exhibit 1 is a copy of an August 11, 2006 letter from Linda A. Wadler to Daniel N. Kassabian.

3. Attached hereto as Exhibit 2 is a copy of an August 22, 2006 letter from Robert Pollack to Daniel N. Kassabian.

4. Attached hereto as Exhibit 3 is a copy of an August 22, 2006 e-mail from Henry C. Dinger to Mary B. Matterer.

5. Attached hereto as Exhibit 4 is a copy of an August 28, 2006 letter from Linda A. Wadler to Mary B. Matterer.

6. Attached hereto as Exhibit 5 is a copy of an August 23, 2006 letter from Mary B. Matterer to Linda A. Wadler.

7. Attached hereto as Exhibit 6 is a copy of an August 28, 2006 letter from Samuel F. Ernst to Linda A. Wadler.

8. Attached hereto as Exhibit 7 is a copy of a July 12, 2006 letter from Daniel N. Kassabian to Linda A. Wadler.

9. Attached hereto as Exhibit 8 is a copy of the Memorandum of Law in Support of Defendants' Objections to the Order of Magistrate Judge Shwartz, Entered on May 13, 2005, Denying Leave to File Amended Answers filed on June 2, 2005 in *Wyeth v. Teva Pharmaceutical U.S.A., Inc and Teva Pharmaceutical Industries Ltd.*, Civil Action No. 03-1293 (FSH) in the United Sates District Court for the District of New Jersey.

10. Attached hereto as Exhibit 9 is a copy of Plaintiff's Response to Defendants' Objections to the Order of Magistrate Judge Shwartz Denying Leave to File Amended Answers. filed on June 13, 2005 in *Wyeth v. Teva Pharmaceutical U.S.A., Inc and Teva Pharmaceutical Industries Ltd.*, Civil Action No. 03-1293 (FSH) in the United Sates District Court for the District of New Jersey.

11. Attached hereto as Exhibit 10 is a copy of an August 29, 2006 letter from Linda A. Wadler to Samuel F. Ernst.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct and that this declaration was executed on this thirty-first day of August, 2006 at Wilmington, Delaware.

MARY B. MATTERER (I.D. No. 2696)

CERTIFICATE OF SERVICE

I hereby certify that on the 31st day of August, 2006, I electronically filed the foregoing document, **REPLY DECLARATION OF MARY B. MATTERER IN SUPPORT OF IMPAX'S MOTION TO MODIFY SCHEDULING ORDER** with the Clerk of the Court using CM/ECF which will send notification of such filing to the following:

Jack B. Blumenfeld
Karen Jacobs Louden
Morris Nichols Arsht & Tunnell
1201 N. Market Street
Wilmington, DE 19801

Additionally, I hereby certify that on the 31st day of August, 2006, the foregoing document was served as indicated on the following:

VIA EMAIL AND HAND DELIVERY
Jack B. Blumenfeld
Karen Jacobs Louden
Morris Nichols Arsht & Tunnell
1201 N. Market Street
Wilmington, DE 19801

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Linda A. Wadler
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202.408.4000
Bill.Lewris@finnegan.com
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/s/ Mary B. Matterer
Mary B. Matterer (I.D. No. 2696)
Morris James Hitchens & Williams LLP
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Attorneys for IMPAX LABORATORIES, INC.

EXHIBIT 1

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TO		FROM	
Name:	Daniel N. Kassabian, Esq.	**Name:**	Linda A. Wadler, Esq.
Firm:	Heller Ehrman LLP	**Phone No.:**	(202) 408-4037
Fax No.:	415-772-1796	**Fax # Verified by:**	A. Norris - MD 8113
Phone No.:	415-772-6098	**# Pages (incl. this):**	3
Subject:	Wyeth v. Impax	**Date:**	August 11, 2006
		Our File No.:	

Confirmation Copy to Follow: NO

Message:

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FINNEGAN HENDERSON FARABOW GARRETT & DUNNER LLP

901 New York Avenue, NW ▪ Washington, DC 20001-4413 ▪ 202.408.4000 ▪ Fax 202.408.4400
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LINDA A. WADLER
202.408.4037
linda.wadler@finnegan.com

August 11, 2006

Daniel N. Kassabian, Esq.
Heller Ehrman LLP
333 Bush Street
San Francisco, CA 94104

Via Facsimile

Wyeth v. Impax Laboratories, Inc., Civil Action No.: 06-222 (D. Del.)

Dear Daniel:

Thank you for your letter of August 9, 2006, confirming that the gap between Bates Nos. 000321 and 000340 in Impax's ANDA does not indicate that pages are missing from the ANDA as filed.

With respect to the remainder of your August 9th letter, we note that WYETH 004-000872 through 907 consists largely of the cover pages and tables of contents for NDA volumes 1.5 through 1.12. As is readily apparent from the tables of contents, NDA volumes 1.5 through 1.12 relate to batch records for selected batches of Venlafaxine Hydrochloride ER Capsules.

Wyeth has already produced over 86,000 pages of its NDA to Impax and objects to the further production of materials for which Impax has no particularized need. In particular and as stated in our objections to Impax's document requests, Wyeth objects to the blanket production of all batch records, as well as, for example, manufacturing records, specifications and analytical methods for venlafaxine hydrochloride itself, stability, toxicology, packaging, quality control, plant layouts and voluminous raw patient data from which patient identifying information must be redacted as overly broad, irrelevant, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence. Nevertheless, if Impax can articulate a particular need for selected information identified in the table of

contents associated with an NDA volume number, we will consider your request on a case-by-case basis.

Sincerely,

Linda A. Wadler

LAW/RAP/amn

cc: Mary B. Matterer, Esq. (via Facsimile)
Richard K. Herrmann, Esq. (via Facsimile)

EXHIBIT 2

FINNEGAN
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GARRETT &
DUNNER LLP

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ROBERT POLLOCK
202.408.4081
robert.pollock@finnegan.com

August 22, 2006

LETTER ONLY VIA FACSIMILE
CONFIRMATION WITH ENCLOSURES
VIA FEDERAL EXPRESS

Daniel N. Kassabian, Esq.
Heller Ehrman LLP
333 Bush Street
San Francisco, CA 94104

Wyeth v. Impax Laboratories, Inc., Civil Action No.: 06-222 (D. Del.)

Dear Daniel:

As part of Wyeth's continuing document production, and as part of our rolling production, I am enclosing one box containing transcripts from the depositions of inventors Clark, Lamer, Sherman and White, and Wyeth's 30(b)(6) witnesses, Alaburda and Mangano, in the Wyeth v. Teva litigation. The enclosed transcripts bear the following range of production numbers:

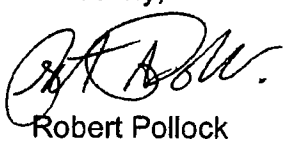
WYETH 300-000001 - WYETH 300-002043.

We are still processing the exhibits marked at the above depositions, but will produce them to you in the near future.

The enclosed documents are stamped CONFIDENTIAL or HIGHLY CONFIDENTIAL and SUBJECT TO PROTECTIVE ORDER. Until a formal protective order is in place, however, the enclosed documents should be maintained on an outside counsel eyes only basis pursuant to D. Del. L.R. 26.2.

Our cost for copying the enclosed documents is $122.58 (6¢ per page). Please reimburse us promptly for this amount.

Sincerely,



Robert Pollock

RAP/bf

cc: Mary B. Matterer, Esq. (via Facsimile, without enclosures)
Richard K. Herrmann, Esq. (via Facsimile, without enclosures)

EXHIBIT 3

Gonzales, Victor M.

From: Dinger, Henry C [hdinger@goodwinprocter.com]
Sent: Tuesday, August 22, 2006 7:22 AM
To: Matterer, Mary B.
Subject: RE: Wyeth v. Impax (transcripts from Teva litigation)

Ms. Matterrer--

I have been in touch with Wyeth's counsel on this subject. They have agreed to assemble the documents that you seek and we have agreed on Teva's behalf to identify those portions that contain Teva confidential information, which portions will be redacted. We have no objection to Wyeth's production of the redacted documents.

--Henry Dinger

Henry C. Dinger, P.C.
Goodwin Procter LLP
Exchange Place
Boston, MA 02109
tel: 617-570-1276
fax: 617-523-1231
e-mail: hdinger@goodwinprocter.com

-----Original Message-----
From: Matterer, Mary B. [mailto:MMatterer@morrisjames.com]
Sent: Tuesday, August 22, 2006 10:20 AM
To: Dinger, Henry C
Subject: Wyeth v. Impax (transcripts from Teva litigation)

Dear Mr. Dinger:
I am just following up on my voicemail from yesterday, inquiring as to whether Teva will agree to release the Teva confidential information in transcripts from the Wyeth v. Teva litigation.

Regards,
Mary Matterer

Mary B. Matterer, Esq.
Morris, James, Hitchens & Williams LLP
222 Delaware Avenue, 10th Floor
P.O. Box 2306
Wilmington, DE 19899-2306
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EXHIBIT 4

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Facsimile
(202) 408-4400

FACSIMILE TRANSMITTAL

TO		FROM	
Name:	Daniel N. Kassabian, Esq.	**Name:**	Robert A. Pollock, Esq.
Firm:	Heller Ehrman LLP	**Phone No.:**	(202) 408-4081
Fax No.:	415-772-1796	**Fax # Verified by:**	A. Norris - MD 8113
Phone No.:	415-772-6098	**# Pages (incl. this):**	3
Subject:	Wyeth v. Impax	**Date:**	August 28, 2006
		Our File No.:	

Confirmation Copy to Follow: NO

Message:

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FINNEGAN HENDERSON FARABOW GARRETT & DUNNER LLP

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LINDA A. WADLER
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linda.wadler@finnegan.com

August 28, 2006

Via Facsimile

Mary B. Matterer, Esq.
Morris, James, Hitchens & Williams, LLP
222 Delaware Avenue, 10th Floor
Wilmington, Delaware 19801-1621

Wyeth v. Impax Laboratories, Inc., Civil Action No.: 06-222 (JJF) (D. Del.)

Dear Mary:

Your letter of August 23, 2006 is unclear in its reference to "all requested materials from the Teva litigation." Wyeth has agreed to produce, and in fact has produced to Impax, the transcripts and accompanying exhibits from the depositions of the inventors and Rule 30(b)(6) witnesses, Alaburda and Mangano. Based upon the underlying e-mails attached to your letter, those documents appear to be what you mean by "all requested materials." Wyeth produced those transcripts and exhibits in response to Impax's expedited request, after assuring itself that they did not contain Teva confidential information, because it had agreed to produce those documents in its July 26, 2006 response to Impax's First Set of Document Requests.

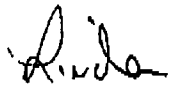
Just so the record is clear, however, Wyeth has not agreed to produce "all requested materials from the Teva litigation with only that [Teva confidential information] redacted," if what you mean by "all requested materials" is all of the materials sought by Impax's document requests.

As stated in Wyeth's opposition to Impax's motion to compel, Impax has demanded production of every scrap of paper from the Teva litigation involving both a different party and different product than this case. Yet Impax has failed to articulate the relevance of documents concerning issues other than claim construction or validity of the patents in suit. Information regarding Teva, its product, and its infringement is simply irrelevant to this litigation. Wyeth maintains these objections.

Wyeth has agreed to produce deposition transcripts of Wyeth's fact witnesses and exhibits from those depositions; Teva's 35 U.S.C. § 282 Notice; Markman briefing; portions of expert reports, expert depositions and contention interrogatory answers concerning validity; and Teva's proposed amended answer on enforceability *once Teva has redacted its confidential information or given Wyeth permission to produce those documents in unredacted form.*

If this letter is unclear in any way, please let us know.

Sincerely,



Linda A. Wadler

LAW/amn

cc: Daniel N. Kassabian, Esq.(via facsimile)
Henry C. Dinger, Esq. (via facsimile)

EXHIBIT 5

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222 Delaware Avenue, 10th Floor
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Facsimile (302) 571-1750
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Mary B. Matterer
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mmatterer@morrisjames.com

Mailing Address
P.O. Box 2306
Wilmington, DE 19899-2306

August 23, 2006

BY EMAIL AND FEDERAL EXPRESS
Linda A. Wadler, Esq.
Finnegan, Henderson, Farabow
Garrett & Dunner LLP
901 New York Avenue
Washington, DC 20001-4413

RE: *Wyeth v. Impax Laboratories, Inc.*, Civil Action No. 06-222 JJF

Dear Ms. Wadler:

It is our understanding that Teva has agreed to specifically delineate any of its confidential information that requires redaction, and that Wyeth will then produce all requested materials from the Teva litigation with only that information redacted. (See attached correspondence from Mr. Dinger.) Apparently in accord with this understanding, Wyeth has recently produced inventor and Rule 30(b)(6) depositions from the Teva litigation that are responsive to Impax's first set of document requests. Please let us know if our understanding is incorrect in any way. If not, we will inform the Court in our upcoming reply brief that Impax's motion to compel as to redacted documents from the Teva litigation is now moot. Thank you for your cooperation in this respect.

Sincerely yours,

Mary B. Matterer

Attachment
cc: Jack B. Blumenfeld (via email w/attachment)

Hadley, Susan C.

From: Dinger, Henry C [hdinger@goodwinprocter.com]
Sent: Tuesday, August 22, 2006 10:22 AM
To: Matterer, Mary B.
Subject: RE: Wyeth v. Impax (transcripts from Teva litigation)

Ms. Matterrer--

I have been in touch with Wyeth's counsel on this subject. They have agreed to assemble the documents that you seek and we have agreed on Teva's behalf to identify those portions that contain Teva confidential information, which portions will be redacted. We have no objection to Wyeth's production of the redacted documents.

--Henry Dinger

Henry C. Dinger, P.C.
Goodwin Procter LLP
Exchange Place
Boston, MA 02109
tel: 617-570-1276
fax: 617-523-1231
e-mail: hdinger@goodwinprocter.com

-----Original Message-----
From: Matterer, Mary B. [mailto:MMatterer@morrisjames.com]
Sent: Tuesday, August 22, 2006 10:20 AM
To: Dinger, Henry C
Subject: Wyeth v. Impax (transcripts from Teva litigation)

Dear Mr. Dinger:
I am just following up on my voicemail from yesterday, inquiring as to whether Teva will agree to release the Teva confidential information in transcripts from the Wyeth v. Teva litigation.

Regards,
Mary Matterer

Mary B. Matterer, Esq.
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****

IRS CIRCULAR 230 DISCLOSURE:
To ensure compliance with requirements imposed by the IRS, we inform you that any U.S. tax advice contained in this communication (including any attachments) is not intended or written to be used, and cannot be used, for the purpose of (i) avoiding penalties under the Internal Revenue Code or (ii) promoting, marketing or recommending to another party any transaction or matter addressed herein.

****

EXHIBIT 6

HellerEhrman LLP

August 28, 2006

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Direct Fax +1.415.772.1759
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Fax +1.415.772.6268

40443.0005

Linda A. Wadler, Esq.
Finnegan, Henderson, Farabow,
Garrett & Dunner, L.L.P.
901 New York Ave., N.W.
Washington, DC 20001

Re: *Wyeth v. Impax Laboratories, Inc.*, No. 06-222 (D. Del.)

Dear Linda:

We are in receipt of your two-sentence letter of August 28. We are perplexed by your comment that our letter of August 21, 2006 did not "substantively respond to the majority of concerns" Wyeth has raised regarding Impax's discovery responses. Our letter of August 21 consisted of six pages of substantive, point-by-point response to each of the issues Wyeth has raised concerning Impax's discovery responses. Impax also raised deficiencies in Wyeth's discovery responses and suggested several compromise solutions. Your letter fails to acknowledge or address any of these points.

Because we cannot understand what you mean by saying we have failed to "substantively respond," and because your two-sentence letter certainly does not constitute a response to the concerns or compromise offers we have raised, we suggest that the best way to resolve the issues both parties have raised regarding each other's discovery responses is to have a telephonic meet-and-confer on these topics. We are available for meet and confer during the following times this week:

- Tuesday, August 29 between 12 p.m. and 6 p.m. EST.
- Thursday, August 31 between 1:30 p.m. and 3:00 p.m. EST and between 4:30 p.m. and 9:00 p.m. EST.
- Friday, September 1 between 12 p.m. and 9 p.m. EST.

Please advise us if you are available for meet and confer during any of these times.

Finally, despite the fact that we provided you a draft protective order seven weeks ago, on July 12, you still have not told us whether Wyeth agrees to its terms. On August 21 we sent you our proposed protective order again with a few modifications. Please inform us by the close of business tomorrow whether Wyeth agrees to the terms of our proposed order or whether there are changes Wyeth would make to the order. If we do not have your response on this issue by the end of this week, we will be forced to move the Court for the entry of our protective order based on Wyeth's seven weeks of silence.

Sincerely,

Samuel F. Ernst

08/28/2006 15:33 FAX 001

****
*** TX REPORT ***
****

TRANSMISSION OK

TX/RX NO	0237
CONNECTION TEL	43#0005#12024084400#
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ST. TIME	08/28 15:32
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RESULT	OK

Facsimile Transmittal

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To: Linda A. Wadler, Esq., Finnegan Henerson, et al., Washington, D.C.
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From: Samuel F. Ernst
Telephone: +1.415.772.6964

No. of Pages: 3 (including cover)
Date: August 28, 2006

40443.0005 (8004)

Message:

SF 1290979 v1
8/28/06 3:32 PM (40443.0005)

EXHIBIT 7

HellerEhrman LLP

July 12, 2006

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40443.0005

Via E-mail and U.S. Mail

Linda A. Wadler, Esq.
Finnegan Henderson Farabow Garrett & Dunner LLP
901 New York Avenue, NW
Washington, DC 20001-4413

Re: Wyeth v. Impax Laboratories, Inc.
U.S. District Court, District of Delaware, Civil Action No. 06-222 JJF

Dear Linda:

I write in response to your letter dated July 10, 2006, regarding the exchange of confidential information. We agree that, until the entry of a suitable protective order in this action and its designation pursuant thereto, the information to be exchanged this Friday will be treated as "outside counsel eyes only" and will not to be used for any purpose other than in connection with this action. Indeed, the Court's Local Rule 26.2 requires as much for any documents deemed and designated as confidential by the producing party prior to the entry of a protective order, so that production is not delayed due to confidentiality concerns.

With respect to a proposed protective order, I am attaching a draft that we have prepared for your review. I hope we can reach an agreement on such an order prior to the parties' production of documents and things.

Best regards,

Daniel N. Kassabian

Attachment

cc: M. Patricia Thayer, Esq.
Jessica R. Wolff, Esq.
Mary B. Matterer, Esq.
Basil J. Lewris, Esq.
Jack B. Blumenfeld, Esq.
Karen Jacobs Louden, Esq.

EXHIBIT 8

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

DOCUMENT ELECTRONICALLY FILED

WYETH,	)
	)
Plaintiff,	)Civil Action No. 03-1293 (FSH)
	)
v.	)**Highly Confidential Pursuant to**
	)**Protective Order**
TEVA PHARMACEUTICALS USA, INC. and	)
TEVA PHARMACEUTICAL INDUSTRIES	)**Return Date: June 27, 2005**
LTD.,	)
	)
Defendants.	)
	)

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' OBJECTIONS TO THE ORDER OF MAGISTRATE JUDGE SHWARTZ, ENTERED ON MAY 13, 2005, DENYING LEAVE TO FILE AMENDED ANSWERS

LITE DEPALMA GREENBERG & RIVAS, LLC
Allyn Z. Lite (AL-6774)
Michael E. Patunas (MP-2306)
Two Gateway Center, 12th Floor
Newark, New Jersey 07102-5003
(973) 623-3000

GOODWIN PROCTER LLP
Henry C. Dinger, P.C.
Daryl L. Wiesen
Lana A. Shvartsman
Melissa L. Paddock
Exchange Place
Boston, MA 02109
(617) 570-1000

Attorneys for Defendants

TABLE OF CONTENTS

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TABLE OF AUTHORITIES

FEDERAL CASES

SECONDARY AUTHORITY

FEDERAL RULES

LOCAL CIVIL RULES

PRELIMINARY STATEMENT

Defendants, Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. ("Teva") respectfully submit this memorandum of law in support of their objections to the Order of the Honorable Patty Shwartz, U.S.M.J., incorporating the opinion delivered on the record on May 9, 2005 and entered on May 13, 2005 ("Opinion") (attached to the Declaration of Michael E. Patunas ("Patunas Decl.") dated May 27, 2005, as Exhibit A), denying Teva leave to amend its answers[1] as clearly erroneous and contrary to law pursuant to the Fed. R. Civ. P. 72(a) and Local Civil Rule 72.1(c)(1)(A).

On April 1, 2005, pursuant to the Order entered on March 22, 2005 allowing Teva to file a motion for leave to amend answers, Teva filed a motion to amend its answers to add an affirmative defense of unenforceability due to inequitable conduct committed by Plaintiff Wyeth ("Wyeth") during prosecution of applications which resulted in the patents Wyeth asserts against Teva in this law suit. Teva's proposed amended answers sought to conform its defenses to the evidence obtained during discovery. The Magistrate Judge, in her Opinion, denied Teva's motion under Rule 16(b) and made certain observations under Rule 15(a).

Teva respectfully objects to the Magistrate Judge's ruling that, under Rule 16(b), Teva unduly delayed in seeking to amend its answers. As more fully set forth below, Teva reasonably sought to investigate its allegations of inequitable conduct through Wyeth's witnesses and documents, as required by Rules 9 and 11 of the Federal Rules of Civil Procedure. Teva could not, consistent with the requirements of Rules 9 and 11, reasonably have been expected to assert

---

[1] Copies of the proposed amended answers of Teva USA and Teva Ltd. are attached to Lana Shvartsman Declaration ("Shvartsman Decl.") dated April 1, 2005, as Exhibits B and C, respectively.

this defense before the Court's original deadline for the amendment of pleadings of December 31, 2003.

In addition, Teva objects to the Court's observation under Rule 15(a) that Wyeth would be unduly prejudiced by the amendment. Teva's amendment will not prejudice Wyeth. The allegation of inequitable conduct arises directly from Wyeth's witnesses and documents revealing misrepresentations made to the United States Patent and Trademark Office ("PTO") during prosecution of Wyeth's three patents. All the evidence Wyeth needs to defend is in its own possession. Wyeth will not require any additional discovery of Teva to prepare its case.

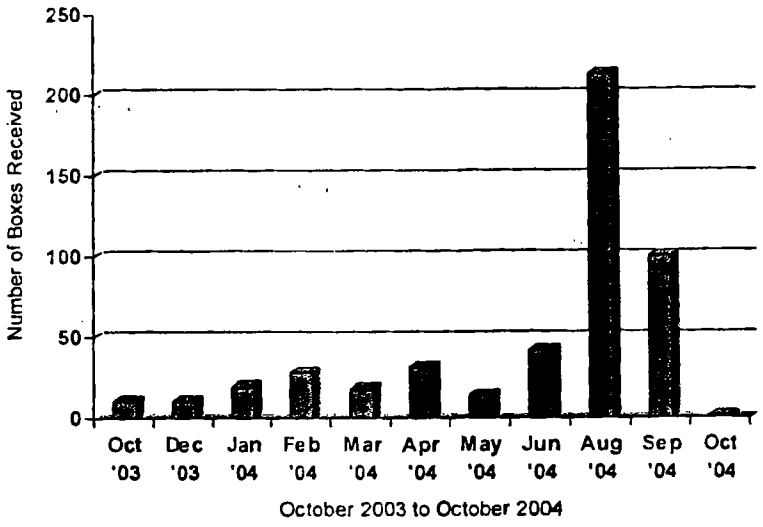
Teva also objects to the Court's observation under Rule 15(a) that Teva's proposed amendment would have been futile. As more fully described below, Teva's allegation of inequitable conduct would have withstood a motion to dismiss.

STATEMENT OF RELEVANT FACTS

Teva moved to amend its answers, pursuant to Fed. R. Civ. P. 15(a), in light of evidence produced in discovery demonstrating that Wyeth committed, inequitable conduct during prosecution of the applications which matured into the patents-in-suit. Teva was required by law to have a good faith basis for asserting this defense ***before*** it added the proposed amendments, and, since the inequitable conduct defense requires allegations of intent to deceive that must be pleaded with particularity, *Ferguson Beauregard/Logic Controls, Division of Dover Resources, Inc. v. Mega Systems, LLC,* 350 F.3d 1327, 1344 (Fed. Cir. 2003), delaying until particularized allegations could be made was essential. *See* Fed.R.Civ.P. 9(b) and 11. Teva deferred amendment of its answers until it had developed the factual underpinnings required to assert the inequitable conduct defense. These factual underpinnings were not sufficiently developed until Teva deposed each of the four Wyeth inventors and two Rule 30(b)(6) designees on the subject

of invention and clinical trials. Judge Shwartz denied Teva's leave to amend its answers largely based on her finding that "Teva had possession of the information upon which it now relies for its proposed amendment. Allowing an amendment at this time would be contrary to policy consideration that favor the closing of the pleadings, encourages certainty to litigation, and admonish delay." Opinion Tr. at 91: 10-16 (attached to Patunas Decl. as Exhibit A). Respectfully, we disagree.

This case was initiated at the end of March 2003, but discovery, and, most pertinently, Wyeth's document production, did not begin in earnest until well into 2004. Before the December 31, 2003 deadline originally set by the Court for the amendment of pleadings, Wyeth produced only 20 boxes of documents, or less than 5% of Wyeth's document production, which totaled 485 boxes on October 4, 2004. The graph below illustrates the pattern of Wyeth's document production.



It took Wyeth a full year from its initial production on October 31, 2003, to substantially complete producing in excess of 1,200,000 pages of documents on October 4, 2004. Upon obtaining a majority of Wyeth's documents by October 2004, Teva immediately commenced depositions of the inventors named on the patents-in-suit, starting with Mr. Stephen White, on October 8, 2004. Through October and into November 2004, Teva deposed each of the four inventors listed on the patents-in-suit and inquired regarding the basis for the statements made in the patents concerning reduced nausea and emesis. None of the four inventors had any knowledge about the basis for those statements. Pursuant to the procedure agreed upon at the August 5, 2004 hearing before Judge Shwartz, Teva promptly noticed depositions of Wyeth concerning the basis of the statements made in the patents-in-suit, among other topics, on November 16, 2004 (Notice of Rule 30(b)(6) deposition on clinical trials, attached as Exhibit F to the Shvartsman Decl.) and on December 2, 2004 (Notice of Rule 30(b)(6) deposition on invention, attached as Exhibit G to the Shvartsman Decl.). Wyeth did not make its Rule 30(b)(6) witnesses available for Teva to examine until February 4, 2005 (Dr. Mangano) and February 18, 2005 (Mr. Alaburda), respectively. Teva also noticed a deposition of Richard Rudolph, a former Wyeth employee who oversaw clinical trials of the extended release venlafaxine product, on January 19, 2005. Teva deposed Dr. Rudolph on February 8, 2005. For ease of reference, Teva has set forth below the chronology of facts relevant to this motion.

Date	**Action**
March 27, 2003	Wyeth filed a lawsuit against Teva Pharmaceuticals, USA, Inc. ("Teva USA"), alleging infringement of U.S. Patent Nos: 6,274,171, 6,403,120 and 6,419,958;
June 2, 2003	Teva USA filed its answer.

June 30, 2003	Court entered a Pretrial Scheduling Order setting December 31, 2003 as the deadline for amending pleadings.
September 12, 2003	Teva produced a copy of its Abbreviated New Drug Application ("ANDA").
October 31, 2003	Wyeth produced a copy of its New Drug Application ("NDA") (totaling 10 boxes of documents).
December 2, 2003	Wyeth produced additional 10 boxes of documents. Prior to the December 31, 2003 deadline to amend pleadings Teva only had in its possession 20 boxes (of approximately 485 boxes) of Wyeth's documents.
December 23, 2003	Wyeth filed an Amended Complaint for patent infringement against Teva USA and Teva Pharmaceutical Industries Ltd. ("Teva Ltd.").
December 31, 2003	**Last day to amend pleadings.**
February 6, 2004	Teva USA filed its answer to the Amended Complaint.
February 24, 2004	Teva Ltd. filed its answer to the Amended Complaint.
October 4, 2004	Wyeth substantially completed producing more than 1,200,000 pages of documents (totaling approximately 485 boxes).
October 8, 2004	Teva deposed Mr. White, one of the four inventors of the patents-in-suit.
October 14, 2004	Teva deposed Mr. Lamer, second inventor of the patents-in-suit.
October 20, 2004	Teva deposed Ms. Sherman, third inventor of the patents-in-suit.
November 4, 2004	Teva deposed, Mr. Clark, fourth inventor of the patents-in-suit.
November 16, 2004; December 2, 2004	Teva noticed Rule 30(b)(6) depositions regarding statements made in the patents-in-suit.
February 4, 2005	Teva deposed Dr. Mangano as Wyeth's Rule 30(b)(6) witness.

February 8, 2005	Teva deposed a former Wyeth employee, Dr. Rudolph, who oversaw clinical trials;
February 18, 2005	**LAST DAY OF FACT DISCOVERY;** Teva deposed Mr. Alaburda as Wyeth's Rule 30(b)(6) witness.
February 22, 2005	Teva filed a letter brief requesting the Court to allow Teva to file a motion for leave to amend its answers.

It was only after reviewing Wyeth's document production and deposing its witnesses that Teva had a good faith belief and basis for particularized allegations that Wyeth misrepresented its invention to the Patent and Trademark Office. Seven of the thirteen independent claims asserted against Teva claim "a method for providing a therapeutic blood plasma concentration of venlafaxine over a twenty four hour period ***with diminished incidences of nausea and emesis***..." (claims 20, 22 and 23 of the '171 patent; claims 1, 3 and 4 of the '958 patent; and claim 1, of the '120 patent). The only support in the specifications[2] of the patents-in-suit for this claim language is the paragraph in Column 2 of the '171 patent, at lines 46-62. Included in this paragraph is the following assertion concerning results obtained from clinical studies by Wyeth concerning nausea and vomiting: "Venlafaxine ER showed a statistically significant improvement over conventional venlafaxine hydrochloride tablets in two eight-week and one 12 week clinical studies." (Col. 2, ll. 52-55). The evidence uncovered during discovery clearly demonstrated that Wyeth had no support for this statement at the time it was made to the PTO.

[2] The specifications of the three patents-in-suit are the same. Therefore, all references to the patents-in-suit will be made with respect to the specification of the '171 patent only.

It was only after Wyeth completed its document production in October, 2004, that Teva began to suspect Wyeth of misrepresenting the results of its clinical studies to the PTO. Teva sought to confirm its suspicion through the depositions of the inventors and, when they were unable to confirm or deny the existence of clinical studies referenced in the specification, Teva immediately noticed Rule 30(b)(6) depositions. Wyeth provided its Rule 30(b)(6) witnesses, Dr. Mangano and Mr. Alaburda, on February 4 and 18, 2005, respectively, two and a half months after Teva issued the notices. Dr. Mangano and Mr. Alaburda identified three clinical studies that allegedly supported the statement made in the specification: 600B-208-US ("the 208 study"), 600B-209-US ("the 209 study"), and 600B-367-EU ("the 367 study"). *See* Alaburda Tr. 115-118, 146-147 (attached to Shvartsman Decl. as Exhibit I), *see also* Mangano Tr. 26-27, 105-106, 140-141, 153-154 (attached to Shvartsman Decl. as Exhibit J). But none of these three clinical studies actually contained results that correlated with the disclosure in the specification and the claims that the extended release formulation results in a diminished incidence of nausea.

The 208 study was the only study that involved both a group of patients receiving the venlafaxine extended release formulation and a group of patients receiving the conventional tablet formulation. The 208 study, however, showed that the incidence of nausea was exactly the same in the two groups tested: 45%. *See* Mangano Tr. 55-57, 104-106 (attached to Shvartsman Decl. as Exhibit J). The 208 study also contained two other analyses of nausea (directed to "adaptation" and "cumulative severity"). Neither of these analyses reported the results of a statistical analysis showing a statistically significant difference in 1996. Thus, the '208 study showed **no improvement** of the extended release formulation in the incidence of nausea.

The 209 and 367 studies did **not** compare a group of patients receiving the venlafaxine extended release formulation to a group of patients receiving the immediate release tablet

formulation. Neither study compared differences in nausea and emesis between the venlafaxine extended release and immediate release formulations. No comparative results or analyses can be conducted with these studies alone. The studies, therefore, do not support the statement in the specification.

At their depositions, Dr. Mangano and Mr. Alaburda presented brand new, never-before-seen, elaborate calculations and permutations of the original clinical study data purportedly showing a diminished incidence of nausea and emesis. Both witnesses testified that, in preparation for the deposition, they had spoken with a biostatistician employed at Wyeth named Wilfredo Ortega-Leone. Both witnesses provided hand-written notes[3] reflecting conversations with Mr. Ortega-Leone concerning statistical analyses of the 208, 209 and 367 studies, and comparing the results of those studies to results obtained in a series of separate studies with Venlafaxine IR. *See* Alaburda Tr. 35-41 (attached to Shvartsman Decl. as Exhibit I); Alaburda Ex. 204 (attached to Shvartsman Decl. as Exhibit K); Mangano Tr. 20-24 (attached to Shvartsman Decl. as Exhibit J); Mangano Ex. 146 (attached to Shvartsman Decl. as Exhibit L). It was only upon receiving these handwritten notes and the testimony concerning these analyses on February 4 and 18, 2005 that Teva was able to understand Wyeth's alleged basis for the statements made in the specification of the patents-in-suit and confirm that Wyeth did, in fact, misrepresent the evidence it possessed regarding results of its clinical studies at the time the patent application was filed. Teva could not, consistent with the requirements of Rules 9 and 11, have been expected to bring this claim before the Court's original deadline for the amendment of

[3] While the witnesses produced their handwritten notes of these analyses, Wyeth refused to produce any documents underlying the analysis conducted by Mr. Ortega-Leone until this Court ordered the production on March 7, 2005. Wyeth finally produced documents concerning the Ortega-Leone analysis on March 17, 2005.

pleadings of December 31, 2003. Before receipt of these statistical analyses at the depositions themselves, Wyeth had presented no statistical analysis of clinical study data. It was only after offering Wyeth a reasonable opportunity to explain the statement made in the patents-in-suit, and concluding that such an explanation was insufficient, that Teva had reasonably confirmed that a claim of inequitable conduct was justified. *See Enzo Life Sciences, Inc. v. Digene Corp.*, 270 F.Supp.2d 484 (D.Del. 2003); *Douglas Press, Inc. v. Int'l Gamco, Inc.*, 2004 U.S. Dist. Lexis 7606 (N.D. Ill. 2004) (attached to Shvartsman Decl. as Exhibit D); *Go Medical Indus. Pty. Ltd. v. C.R. Bard*, 1995 U.S. Dist. Lexis 22248 (N.D. Ga. 1995) (attached to Shvartsman Decl. as Exhibit E).

ARGUMENT

Pursuant to Local Civil Rule 72.1(c)(1), this Court may modify the Magistrate Judge's Order only if it finds that the ruling was clearly erroneous or contrary to law. *See, e.g., Miller v. Beneficial Mgmt. Corp.*, 844 F.Supp. 990, 997-98 (D.N.J. 1993) (reversing Magistrate Judge's decision and permitting amendment of pleading).

I. TEVA HAS NOT UNDULY DELAYED IN SEEKING TO AMEND ITS ANSWERS

The Magistrate Judge, in her Opinion, held that "Teva had possession of the information upon which it now relies for its proposed amendment. Allowing an amendment at this time would be contrary to policy consideration that favor the closing of the pleadings, encourages certainty to litigation, and admonish delay." Opinion Tr. at 91: 10-16 (attached to Patunas Decl. as Exhibit A). This finding is clearly erroneous based on the record before the Court.

Teva moved to amend its answers, pursuant to Fed. R. Civ. P. 15(a) to detail evidence produced in discovery in support of its defense that Wyeth's patents are unenforceable as a

matter of law due to inequitable conduct committed by Wyeth during prosecution of the applications which matured into the patents-in-suit. Teva was required by law to have both a good faith belief in the viability of its defense, and sufficient information to allege the basis for an allegation of inequitable conduct with particularity, ***before*** it added the proposed amendments. *See Ferguson. Beauregard/Logic Controls,* 350 F.3d at 1344 ("inequitable conduct, while a broader concept than fraud, must be pled with particularity"); Fed.R.Civ.P. 9(b) and 11. Teva deferred amendment of its answers until such time that it had developed the factual underpinnings required to assert the inequitable conduct defense. Teva did not believe that these factual underpinnings were sufficiently developed until Teva deposed each of the four of Wyeth's inventors and two Rule 30(b)(6) designees on the subject of invention and clinical trials.

The Magistrate Judge's ruling that Teva could have plead inequitable conduct based on the first boxes of documents containing Wyeth's NDA that Wyeth produced to Teva in October 2003 is based on hindsight.[4] Teva explained that it had to cull through Wyeth's voluminous document production, which Wyeth did not substantially complete until October 2004, before Teva was even able to begin formulating its inequitable conduct defense. Teva needed to depose Wyeth's witnesses in order to satisfy its obligations to investigate a claim of inequitable conduct before alleging it in the proposed amended answers. Therefore, it was only after receiving and reviewing all of Wyeth's documents and deposing Wyeth's witnesses that Teva was able to recognize the significance of (1) none of the four inventors knowing the basis for the disclosure

[4] The Court stated: "The issue here is could you have done it sooner, could you have looked at the information available to you and determined whether or not that evidence existed instead of waiting basically until the last two weeks of discovery..." Opinion Tr. at 40: 15-20.

in the specification and the claims directed to an improved side effect profile, and (2) Wyeth's inablilty to identify any studies that supported the statements made in the specification and the claims directed to "a method for providing a therapeutic blood plasma concentration of venlafaxine over a twenty four hour period with diminished incidences of nausea and emesis..." Similarly, in *Miller,* this Court held that because the defendant was required by law to have good faith belief in the viability of its after-acquired evidence defense to an employment discrimination allegation, "it was therefore reasonable and in fact necessary for Beneficial to delay adding the Proposed Amendments until after Miller Deposition." *Miller,* 844 F.Supp. at 1001.

Moreover, courts have repeatedly recognized that a patent defendant acts properly when it investigates and confirms a claim of inequitable conduct before seeking to amend an answer to assert such a defense. For example, the Court in *Douglas Press* explained that, "allegations of inequitable conduct are serious and we cannot fault Tabaco for waiting for further evidence before filing such an affirmative defense, especially keeping in mind *Rule 11 of the Federal Rules of Civil Procedure*." 2004 U.S. Dist. Lexis at *4 (allowing amendment to assert inequitable conduct) (emphasis in original). Similarly, in *Enzo Life Sciences*, Judge Farnan considered, and rejected, arguments similar to those presented by Wyeth here. 270 F.Supp.2d 484. Judge Farnan concluded that allowing the amendment after investigation was appropriate because "[a]lthough . . . the facts underlying the inequitable conduct allegations were available . . . in the public prosecution history . . ., the Court concludes that since the Rule 9(b) 'pleading with particularity' requirement is implicated with regard to an inequitable conduct claim, [Defendant] was prudent and possibly required to confirm the factual allegations through discovery." *Id.* at 489. *See also Go Medical Indus.*, 1995 U.S. Dist. Lexis 22248, at *16 ("While

defendant may have obtained some information to support its new allegations in September of 1994, this court will not penalize defendant for obtaining additional, confirming information in January 1995 to support its claims -- especially given that Rule 9(b) requires that allegations of fraud, such as inequitable conduct before the U.S. Patent Office, be stated with particularity."). Had Teva moved to amend its answers in December 2003 to include a defense of unenforceability based on inequitable conduct, Wyeth surely would have argued that Teva did not have any evidence of intent because Teva had not yet deposed any of Wyeth's witnesses. But to argue that Teva should have commenced depositions on the basis of only 5% of Wyeth's document production, when Teva was limited to only 10 fact depositions, is unreasonable.

In this case, the passage of time was occasioned by Wyeth's protracted document production, and not by Teva's actions. The Third Circuit has held that the denial of leave to amend cannot be premised on ground of "undue delay" alone: "[t]he passage of time, without more, does not require that a motion to amend a complaint be denied; however, at some point, the delay will become "undue," placing an unwarranted burden on the court, or become "prejudicial," placing an unfair burden on the opposing party." *Adams v. Gould Inc.*, 739 F.2d 858, 868 (3d Cir. 1984), cert. denied, 469 U.S. 1122 (1985). *See also Kiser v. General Electric Corp.*, 831 F.2d 423, 427 (3d Cir. 1987) cert. denied sub nom *Parker-Hannafin Corp. v. Kiser*, 485 U.S. 907 (1988); *In re K-Dur Antitrust Litig.*, 338 F.Supp. 2d 517, 527 (D.N.J. 2004); *Bouton v. BMW of North America, Inc.*, Civ.A. No. 90-2884, 1994 WL 447310, at *12 (D.N.J. April 13), aff'd, 29 F.3d 103 (3d Cir. 1994); *Miller*, 844, F.Supp. at 1000; *Boileau v. Bethelhem Steel Corp.*, 730 F.2d 929, 938 (3d Cir. 1983), *cert. denied*, 469 U.S. 871 (1985) (in the absence of demonstrated prejudice to the non-moving party, District Court erred in refusing an amendment ten years after the complaint was filed); *Leased Optical Departments-Montgomery*

Ward, Inc. v. Opti-Center, Inc., 120 F.R.D. 476, 479 (D.N.J. 1988) ("Delay alone is not sufficient to deny the motion to amend...").

This Court has recognized that although the moving party has the burden of showing "good cause" to amend under Rule 15(a), "disputes are to be tried upon the merits where possible, and parties should generally not be precluded by non-intentional failure to clearly raise claims or defenses, where justice so requires and where prejudice arising from the movant's delay is curable." *Leased Optical,* 120 F.R.D. at 479 and 480. In the case at bar, Teva did not unduly delay in seeking to amend its answers. Teva's ability to assert a defense of inequitable conduct was completely dependent upon the timing of the evidence produced by Wyeth during discovery. In *Leased Optical*, this Court held that "[in] the absence of bad faith or dilatory motive, and where the lengthy delay is explained by the movant's inadvertence, the inquiry turns to whether this tardy amendment causes undue prejudice to defendant." *Id.* at 479. In her Opinion, the Magistrate Judge explicitly stated that there is "no finding by this Court that there was any kind of bad faith... in making the motion or lodging the proposed amendment." Opinion Tr. At 94: 6-8 (attached to Patunas Decl. as Exhibit A).

II. THE COURT'S OBSERVATION THAT WYETH WOULD BE PREJUDICED IS CONTRARY TO LAW

The burden of showing prejudice rests with the party opposing amendment. *See Kiser,* 831 F.2d at 427-28; *Miller,* 844, F.Supp. at 999; *Air Prods. and Chems., Inc. v. Eaton Metal Prods. Co.*, 256 F.Supp. 2d 329, 332 (E.D. Pa 2003). The party opposing amendment "has a heavier burden than merely claiming prejudice," but rather "must show that it [was] unfairly disadvantaged or deprived of the opportunity to present facts or evidence which it would have offered had the [movant's] amendments been timely." *Heyl & Patterson Int'l, Inc. v. F.D. Rich*

Hous. of V.I., Inc., 663 F.2d 419, 426 (3d Cir. 1981); *Mantz v. Chain*, 239 F.Supp. 2d 486, 506 (D.N.J. 2002); *Deakyne v. Comm'rs of Lewes*, 416 F.2d 290, 300 (3d Cir. 1969). *See Cuffy v. Getty Refining & Mktg. Co.*, 648 F.Supp. 802, 806 (D.Del. 1986) (finding that because "an amendment, designed to strengthen the movant's legal position, will in some way harm the [non-movant]," the non-movant must show more in order to establish prejudice). The burden is on Wyeth to establish prejudice beyond mere assertions of things it might have done differently. Wyeth did not meet this burden.

In its Opinion, the Court stated that "[t]he Court need not reach futility or prejudice under Rule 15, but I do want to make a few observations." Opinion Tr. at 93: 2-3 (attached to Patunas Decl. as Exhibit A). The Court made the following "observations:"

> Wyeth had elected not to pursue certain discovery based upon certain agreements between counsel on the IR versus ER issues... It did not pursue investigating anything connected with Anapharm. There has already been a representation by Teva that it really doesn't matter... what Teva knew about the product since the focus about intentional misrepresentation really focused on what Wyeth knew, when it knew it, and what it did or did not tell the Patent Office. But the Court must note that this is an equitable remedy and surely Wyeth would want to be able to introduce whether or not Teva had similar perspectives about the side effects or the decrease in side effects in the formulation when administered to the patients and then they would be able to argue whether or not the representation in the patent, even if it proved to be not accurate, warrants the type of relief that... is being sought by way of unenforceability of declaration of invalidity.

Opinion Tr. 94:13-25 to 95: 1-7 (attached to Patunas Decl. as Exhibit A). The Court's observation is contrary to law. Here, Wyeth will not be prejudiced by Teva's proposed amendments because where a possible defense or counterclaim, not yet pled, could be ***anticipated*** by the opposing party, prejudice is unlikely from an amendment raising the defense or counterclaim. *See Edwards v. Storage Tech Corp.*, 1999 WL 33505545 at * 2 (E.D. Pa.

March 1, 1999) (where a plaintiff can anticipate a defense and counterclaim, or where the need for discovery and the assertion of a counterclaim "should be foreseeable to a plaintiff bringing this action ... there is no indication that [plaintiff] will be unduly prejudiced by this court granting [] leave to file the amended answer.").

In this case, it is clear that Wyeth anticipated a defense and counterclaim of unenforceability due to inequitable conduct. First, Wyeth took extensive discovery concerning Teva's knowledge of nausea and vomiting results with venlafaxine. Wyeth deposed two of Teva's witnesses who oversaw Anapharm's bioequivalence studies submitted by Teva to the FDA in this case: Dr. Elkoshi and Mr. Cardullo. Wyeth questioned these witnesses extensively regarding their experience with Teva's venlafaxine products.

Second, Wyeth prepared its two Rule 30(b)(6) witnesses to present Teva with brand new statistical analyses concerning nausea and vomiting data, purporting to show that there is "statistically significant improvement" of nausea and vomiting between IR and ER formulations. This new data bore no relation to the documents produced by Wyeth in October 2003 because in October 2003 Wyeth had no data to show the statistically significant improvement of nausea and vomiting.

Third, the fact that Wyeth had been well aware that it did not have the clinical trial results claimed in the patents-in-suit and had been attempting to create support for the claims to "diminished incidences of nausea and emesis" is further illustrated by Wyeth's submission to the FDA on September 23, 2004, of a revised and corrected version of the final report of the 208 study to the Food and Drug Administration ("FDA") with "minor corrections" (excerpts attached to Shvartsman Decl. as Exhibit N). The only "corrections" were to provide two revised analyses of data concerning nausea. Compare Alaburda Ex. 207 (excerpts of original version of 208

study from 1996) (attached to Shvartsman Decl. as Exhibit M) with Alaburda Ex. 208 (excerpts of 2004 version of 208 study) (attached to Shvartsman Decl. as Exhibit N). *See also* Alaburda Tr. 133-143 (attached to Shvartsman Decl. as Exhibit I).

Wyeth's conduct throughout this litigation plainly demonstrates that Wyeth fully anticipated Teva's defense and counterclaim of inequitable conduct. To argue that Wyeth would be prejudiced by not taking any further fact discovery of Teva on the issue of **Wyeth's** misrepresentation to the Patent Office concerning **Wyeth's** data on the diminished incidence of nausea and vomiting is disingenuous. The meritlessness of this argument is furthermore exacerbated by Wyeth's March 1, 2005 letter to the Court, admitting that Wyeth has already developed the evidence it needs on the issue of inequitable conduct: "As part of its case, Wyeth has developed evidence to establish that Effexor® XR is surprisingly better than immediate release dosage form of venlafaxine hydrochloride, including better with respect to the side effects of nausea and vomiting." Wyeth's March 1, 2005 letter to the Court at 9. Thus, Wyeth will not be "unfairly disadvantaged or deprived of the opportunity to present facts or evidence" if the amendment is allowed. *See Heyl & Patterson Int'l*, 663 F.2d at 426.

Waiting until the factual investigation was complete to file the motion to amend has not prejudiced Wyeth. "[U]njustified delay and bad faith in seeking an amendment could not defeat a motion to amend without a showing that the delay caused actual prejudice to the non-moving party." *Miller,* 844 F. Supp. at 999. Thus, "even if [defendant's] delay in adding the Proposed Amendments were found to be 'undue' or unexplained, such a finding would be insufficient grounds to deny [defendant] leave to amend the Answer." *Miller,* 844 F.Supp. at 1000; *see also Fingermates, Inc. v. Nailtiques Cosmetic Corp.* 1996 WL 901967 *4 (D.N.J. Dec. 16, 1996) ("While the failure to bring a timely motion to amend could prejudice a non-moving party, the

Third Circuit has made it clear that any such delay must rise to the level of unfair prejudice."). Here, as discussed above, there can be no prejudice to Wyeth. The question raised by Teva's proposed defense addresses only what Wyeth knew and when Wyeth knew it. Wyeth has had access to all of this information, and no further discovery is required on the issue of whether Wyeth engaged in inequitable conduct during the prosecution of its patents.

III. THE COURT'S OBSERVATION THAT TEVA'S CLAIM IS FUTILE IS CLEARLY ERRONEOUS

The Court's observation that "Teva's allegation, at least in my view, may not have withstood a 12(b)(6) motion and the proposed amendment would, therefore, have been deemed futile, had the Court reached the Rule 15 analysis" is clearly erroneous. As shown below, Teva's proposed amendments are not futile.

This Court has stated that "if the proposed amendment is 'frivolous or advances a claim or defense that is legally insufficient on its face, the court may deny leave to amend. If a proposed amendment is not clearly futile, then denial of leave to amend is improper.'" *Harrison Beverage Co. v. Dribeck Importers, Inc.*, 133 F.R.D. 463, 468 (D.N.J. 1990) *citing* Wright, Miller & Kane, *Federal Practice & Procedure* § 1487 at 637-642 (2d ed. 1990). Under this standard, this Court held in *Miller* that "the court 'must accept as true the allegations in the [defendant's] proposed affirmative defenses and construe those allegations in the light most favorable to the [defendant].'" *Miller,* 844 F. Supp. at 1001, *citing Fireman's Fund Insurance Co. v. Krohn*, No. 91 Civ. 3546, 1993 WL 299268 at *4 (S.D.N.Y. 3 Aug. 1993); *Northwestern National Insurance Co. of Milwaukee v. Alberts*, 717 F.Supp. 148, 153 (S.D.N.Y. 1989); *Kulwici v. Dawson*, 969 F.2d 1454, 1462 (3d Cir. 1992) ("On review of a motion to dismiss for failure to state a claim, we look only to the complaint to see whether there is any set of facts plaintiff can

prove that would support [his or her claim]. All allegations in the complaint must be accepted as true, and the plaintiff must be given the benefit of every favorable inference to be drawn therefrom.").

The question presented by the defense of inequitable conduct is whether Wyeth had support for the claims made in the patent specification at the time it was made. The Federal Circuit has explained that statements made in the past tense in patent specifications concerning examples or experiments are interpreted as statements that the actual experiments were conducted and the results reported were obtained. *Hoffman-La Roche, Inc. v. Promega Corp.*, 323 F.3d 1354, 1364 (Fed. Cir. 2003). Misrepresentations of such evidence can result in a finding that the patent is unenforceable. *Id.* at 1372. Here, the comparative claims for the nausea and vomiting results between venlafaxine extended release and immediate release formulations are in the past tense – "***was*** greatly reduced" and "***showed*** a statistically significant improvement." Despite these statements, Wyeth did ***not*** have three studies that compared the nausea and emesis results of venlafaxine extended release with similar results from venlafaxine immediate release or that showed a "statistically significant" difference.

Teva's proposed defense of inequitable conduct alleges that based on facts obtained during discovery, Wyeth did not have evidence of a "diminished incidence of nausea" as claimed in the patents-in-suit and described in the specification. In fact, Wyeth was aware that it did not have the evidence and Wyeth affirmatively misrepresented to the Patent Office that such evidence existed as a result of three clinical trials. Through discovery, Teva found out and confirmed that the three studies referred to in the specifications of the patents-in-suit were the 208, 209 and 367 studies. The 208 study was the only study that actually compared the incidence of nausea between patients receiving extended release and immediate release

formulations. As stated above, that study concluded that there is no difference in the incidence of nausea between the two different formulations. Instead of informing the Patent Office that the only study that directly compared nausea between Wyeth's extended release and immediate release formulations did not show a diminished incidence of nausea in the extended release formulation, Wyeth misrepresented to the Patent Office that the clinical studies "showed a statistically significant improvement over conventional venlafaxine hydrochloride tablets in two eight-week and one 12 week clinical studies." (The '171 patent at col. 2, ll. 52-55).

The 209 and 367 studies did **not** directly compare the incidence of nausea between patients receiving different formulations. In fact, the 209 study was conducted with the U.S. patients, whereas the 367 study was conducted with the European population. It is well known, and it was well known to Wyeth, that the European population has a significantly greater tolerance threshold for side effects such as nausea and vomiting than the U.S. population. Thus, the incidence of nausea in the European 367 study was 17% compared to the 36% incidence reported for the U.S. 209 study. The difference in nausea between the **same** extended release formulation in two different populations is striking. It was only due to this striking difference that Wyeth is **now** able to come forth with the pooled analysis of the three studies, 208, 209 and 367, to show that there is a statistically significant difference in nausea between the extended release and immediate release formulations. Such manipulation of data is improper and misleading. This information was highly material as the majority of the asserted independent claims contain the claim limitation of "a diminished incidence of nausea and emesis." Upon Teva's challenge of inequitable conduct based on Wyeth's misrepresentations of the clinical studies' results, Wyeth performed a sophisticated manipulation of the clinical study data on the eve of its witnesses' Rule 30(b)(6) depositions and **10 years** after the clinical studies were

conducted, in desperation of avoiding a finding of inequitable conduct. Wyeth's misrepresentation of the results of clinical studies during prosecution of the patents-in-suit constitutes inequitable conduct before the Patent Office and renders the patents-in-suit unenforceable. In the interest of justice, Teva should not be deprived to raise its defense of inequitable conduct.

Based on these facts, it is clearly erroneous to conclude that Teva's defense of inequitable conduct is futile.

CONCLUSION

For the foregoing reasons, Teva's motion to amend should be allowed.

Dated: May 27, 2005

Respectfully submitted

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CONTAINS CONFIDENTIAL AND HIGHLY CONFIDENTIAL INFORMATION PURSUANT TO PROTECTIVE ORDER

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

WYETH, Plaintiff, v. TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICAL INDUSTRIES LTD., Defendants.	Civil Action No.: 03-1293 (FSH)

PLAINTIFF'S RESPONSE TO DEFENDANTS' OBJECTIONS TO THE ORDER OF MAGISTRATE JUDGE SHWARTZ DENYING LEAVE TO FILE AMENDED ANSWERS

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I. PRELIMINARY STATEMENT

More than a year past the deadline for filing a motion to amend the pleadings, and on the eve of the close of fact discovery in a case pending for almost two years, Teva for the first time informed Wyeth and the Court that it intended to seek permission to file a motion to amend its Answers to assert inequitable conduct. After having given Teva repeated opportunities to explain its delay, and having repeatedly failed to do so, the Court provided a detailed ruling on May 9th correctly explaining why Teva failed to satisfy the "good cause" requirement of Rule 16.

Teva's burden on this appeal is to establish that Judge Shwartz's ruling was "clearly erroneous or contrary to law." Fed. R. Civ. P. 72(a). But Teva does not even begin to satisfy the clearly erroneous standard. Teva has not, and cannot, provide any explanation for its delay because there was no "newly discovered evidence." Instead, Teva has had in its possession all of the information on which it now bases its inequitable conduct allegations since October 2003. Teva simply waited until the last day of fact discovery to change its claim construction and assert for the first time an inequitable conduct defense based upon that new claim construction. Moreover, consistent with its briefs and arguments before Judge Shwartz, Teva continues to ignore Rule 16, upon which the Court relied. Consequently, Teva also has failed to establish that there was legal error in the Court's interpretation of Rule 16.

Teva's proposed defense centers on its contention that Wyeth acted inequitably because Wyeth purportedly had no support for a statement in Wyeth's patents that extended release venlafaxine "showed a statistically significant improvement over conventional venlafaxine hydrochloride tablets in two eight-week and one 12 week clinical studies." [U.S. Patent No. 6,274,171, col. 2, ll. 52-55 ("'171 patent")]. But in October 2003, Teva had in its possession Wyeth's support for that statement–Wyeth's NDA. Since that NDA was filed shortly after the

effective filing date of Wyeth's patents, and since Wyeth was required to disclose in its NDA all clinical trials involving its experimental extended release formulation, Teva knew that any clinical trials referred to in the patents must have been included in that NDA. And from the NDA it was apparent that Wyeth had completed only two eight-week (Studies 209 and 367) and one 12 week (Study 208) clinical trials as of the patents' effective filing date. Thus, Teva had all of the facts it now relies upon to allege inequitable conduct in October 2003, well before the December 31, 2003 deadline for amendment of pleadings and long before its belated February 2005 motion for leave to amend.

Teva now argues that "[i]t was only after Wyeth completed its document production in October 2004, that Teva began to suspect Wyeth of misrepresenting the results of its clinical studies to the PTO." [Teva's Memorandum of Law in Support of Defendants' Objections to the Order of Magistrate Judge Shwartz Denying Leave to File Amended Answers ("5/27/05 Br.") at 7]. But Teva previously has represented that the information it had in October 2003 "raised a red flag for us" [May 9, 2005 Hearing Transcript ("5/9/05 Tr.") at 6], and that it had been trying to develop an inequitable conduct defense since "August 2003." [Teva's 2/22/05 letter to Judge Shwartz ("2/22/05 ltr.") at 2]. Nevertheless, Teva did not even serve an interrogatory on Wyeth regarding the support for the statement in the patents that Teva now questions. Instead, it waited for over 15 months after this supposed "red flag" arose before first notifying the Court and Wyeth of its intentions to amend its pleadings to allege inequitable conduct. Thus, Judge Shwartz concluded:

> Teva should have known about the 208, 209, and 367 studies by December of 2003, as it was disclosed to them in October 2003. The Court has not been presented with any information as to why there was any confusion about whether the three studies in the NDA were different than those in the patent application, why there wasn't an inquiry sooner than the last weeks of fact discovery in a case where discovery has been going on for more than a year.

[5/9/05 Tr. at 89]. Teva does not, and cannot, challenge this finding. It is not clearly erroneous.

Teva further argues that it could not have presented its inequitable conduct allegations prior to the February 2005 depositions of Dr. Mangano and Mr. Alaburda (the "February 2005 depositions"). According to Teva, until those depositions it was not able to understand "Wyeth's alleged basis for the statements made in the specification of the patents-in-suit and confirm that Wyeth did, in fact, misrepresent the evidence it possessed regarding results of its clinical studies at the time the patent application was filed." [5/27/05 Br. at 8]. But Teva's inequitable conduct allegations are not based on testimony from the February 2005 depositions. Instead, those depositions presented clear evidence supporting the truthfulness of the statement in the patents. Rather, Teva conceded that all it "learned" from the February 2005 depositions was a confirmation of what it already knew--that the three completed clinical trials identified in the NDA (studies 208, 209 and 367) were the clinical studies referred to in the patents. [5/9/05 Tr. at 51, 79]. Teva cannot explain why it waited over a year to notice the depositions it took in February 2005 to "confirm" what it knew in October 2003. Nor can it explain why it did not serve an interrogatory if it believed it needed such "confirmation." As Judge Shwartz concluded:

> In October or November 2003, Teva had Wyeth's NDA for the extended release formulation from which it could have identified the studies or, at the very least, could have diligently examined whether or not the studies referred to [in] the NDA were those referred to in the patent. So the Court does not find that waiting until February 2005 to solidify that fact was a diligent use of one's time.

[5/9/05 Tr. at 89-90]. Teva has not shown this finding to be clearly erroneous.

Moreover, Teva has provided no explanation, nor can it provide any explanation, of why it chose to ignore the Court's December 2003 deadline. As Judge Shwartz found:

> Thus, it appears to this Court that there was sufficient information long before February 2005 for which--upon which Teva could have sought leave or at least could have come before this Court and sought an extension at that time. In short, it appears that, at least from October 2003, Teva had possession of the information upon which it now relies for its proposed amendment.

[5/9/05 Tr. at 91]. Again, this finding is not clearly erroneous.

Finally, although Judge Shwartz based her May 9th ruling on Rule 16, she also made a number of observations regarding the standards of Rule 15. Specifically, the Court correctly found that Teva's last-minute dispute of the differences in side effects between the immediate release and extended release formulations deprived Wyeth of the ability to take further discovery on Teva's clinical experiences with the two dosage forms, its knowledge of the differences in nausea and vomiting, and its practices regarding pooling of data. Judge Shwartz also correctly observed that Teva's motion appeared to be futile as Teva's interpretation of the patents statement at issue was incorrect, that the three studies referred to in the patents when taken together support the statement in the patents, and that Teva had failed to show that the alleged misrepresentation would have been material to the examiner. [5/9/05 Tr. at 99-101]. These observations are supported by the record, providing further support for Judge Shwartz's ruling.

II. BACKGROUND

In a case pending since March 24, 2003, Judge Shwartz issued a Pretrial Scheduling Order stating that "[a]ny motion to amend pleadings must be filed not later than December 31, 2003." [August 1, 2003 Scheduling Order at ¶ 7, emphasis added, Steiner Ex. 1]. On the first day of fact discovery, Wyeth served on Teva an interrogatory asking whether Teva was asserting any unenforceability defense, and for the basis of any such defense. Teva never indicated it would assert such a defense until the last day of fact discovery, February 18, 2005, when it supplemented its earlier response.

Wyeth responded to Teva's first document requests served in August 2003, and despite the massive amount of documents Teva sought on a wide ranging variety of topics, Wyeth produced its Effexor® XR New Drug Application ("NDA") as early as possible, on October 31, 2003. Effexor® XR is Wyeth's extended release venlafaxine formulation. As Teva is well

aware, the Effexor® XR NDA contains detailed information regarding all of the Effexor® XR clinical trials done for or by Wyeth, including the Final Reports for Studies 208, 209 and 367 upon which Teva bases its inequitable conduct allegation. Yet Teva argues that it needed to wait over a year before it could identify the clinical trials that formed the basis for the statement at issue in the patents. [5/27/05 Br. at 2-3, 8]. This is simply not true.

Teva knows full well that FDA regulations *require* NDA applicants to include in their NDA submissions, reports and/or information regarding *all* tests in all human subjects involving the subject formulation of the NDA. Wyeth's NDA therefore must have, by law, included detailed information on each and every clinical trial completed by the filing date of Wyeth's NDA. Significantly, Wyeth's first patent application was filed in March 1996, just prior to the May 1996 filing date of Wyeth's NDA. Thus, in October 2003, Teva knew that the three clinical trials referred to in the March 1996 patent application must also have been included in Wyeth's May 1996 NDA. As a result, Teva knew in October 2003 that it possessed the entirety of clinical trials pertaining to extended release venlafaxine that existed at the time Wyeth filed its patent application. Had Teva believed otherwise, it should have timely requested extension of the December 31, 2003 deadline for amending pleadings.

A quick review of Wyeth's Effexor® XR NDA would have revealed to Teva that only two eight-week clinical trials (Studies 209 and 367) and only one 12 week clinical trial (Study 208) were completed prior to the effective filing date of Wyeth's patents. Their final study reports describing the treatments tested, the analyses performed, and the results obtained were part of Wyeth's NDA, and thus, were in Teva's possession as of October 2003. Teva does not and cannot explain why, in October 2003, it had any remaining question as to the identity of the "two eight-week and one 12 week clinical studies" identified in Wyeth's patents. Indeed, it

was apparent from the NDA cover letter and Table of Contents that Studies 208, 209 and 367 were the only completed studies of 8 week and 12 week durations. [Steiner Ex. 2 at WYETH 004-000002, and Steiner Ex. 3 at WYETH 004-000054, respectively]. While Teva provides a time line at page 3 of its brief that depicts Wyeth's document production as continuing through 2004, and argues that its "ability to assert a defense of inequitable conduct was completely dependent upon the timing of the evidence produced by Wyeth" [5/27/05 Br. at 13], Teva fails to indicate that everything Teva is relying upon for its inequitable conduct theory was produced in October 2003–in the very first document production depicted in Teva's graph. Nor does the graph indicate that, according to Teva, it had been developing an inequitable conduct defense even before the production began.

That Wyeth produced an additional 465 boxes of documents after the October 2003 production of its NDA is wholly irrelevant. The depositions of the inventors and other Wyeth witnesses are equally irrelevant to the identification of the studies referred to in the patents. Teva knew that Wyeth was, by law, required to identify *all* its clinical trials in its NDA. Therefore, any additional documents or deposition testimony could not have identified any "new" clinical trials that could have formed the basis for the statement in the patent.

Moreover, Teva's argument that it "began to suspect Wyeth of misrepresenting the results of its clinical studies" "only after" Wyeth completed its document production, [5/27/05 Br. at 7], is flatly at odds with its other representations to the Court. For example, in February 2005, Teva argued that its theory had not changed and that "Wyeth has been on notice since August 2003 of Teva's efforts to develop an inequitable conduct defense" [2/22/05 ltr. at 2], indicating that Teva had "begun to suspect" Wyeth of inequitable conduct long before the October 2004 completion of production. And Teva took yet another position during the May 9th

hearing as to when it "began to suspect" Wyeth. Specifically, Teva stated at oral argument before Judge Shwartz that its review of Wyeth's NDA documents and supporting materials, which it received in October 2003, "raised a red flag" for Teva. [5/9/05 Tr. at 6]. Teva's many conflicting positions as to why it did not comply with the Rule 16 scheduling order is testament to the fact that there is no valid reason.

In a similar display of inconsistent positions, Teva previously argued that it did not assert inequitable conduct earlier because it wanted to give Wyeth a "reasonable opportunity" to explain the statement in the patents. [Teva's April 1, 2005 Motion for Leave to Amend its Answers ("4/1/05 Br.") at 3]. By contrast, in February, Teva argued that it delayed because, prior to the February 2005 depositions, there was a "serious a question whether Teva possessed facts sufficient to allege inequitable conduct under Federal Circuit precedent or Rule 11." [2/22/05 ltr. at 1]. Not only was there no basis prior to the February 2005 depositions, there still is no basis after those depositions. The February 2005 depositions provided no new evidence upon which Teva now relies to support its inequitable conduct allegation. In any event, if Teva was interested in giving Wyeth a "reasonable opportunity" to explain the statement in the patents, it would have served an interrogatory in 2003.

Instead, Teva waited until February 14, 2005, well over a year after the deadline set by the Court's Rule 16 Scheduling Order, and on the eve of the close of fact discovery, to notify the Court and Wyeth of its intention to assert an inequitable conduct defense. This surprising development was followed four days later by two other dramatic changes in its theories: (1) a complete change in Teva's claim construction of "diminished incidences of nausea and emesis," and (2) a new ground of non-infringement based on Teva's new construction of that claim phrase. All of this was done on the last day of fact discovery, notwithstanding that Teva had

already served its original claim construction eight months earlier on June 15, 2004, and Teva had previously set forth its non-infringement positions on December 5, 2003 in response to Wyeth's interrogatory seeking the basis for any non-infringement allegation.[1]

Teva tries to hide its lack of diligence with a lengthy time line that purports to set forth the "chronology of facts relevant to this motion." [5/27/05 Br. at 4-5]. Most of what Teva includes, however, is wholly irrelevant to this motion. Instead, Wyeth respectfully submits that the following time line more accurately portrays Teva's dilatory conduct.

Date	**Action**
March 27, 2003	• Wyeth brought suit against Teva Pharmaceuticals, USA, Inc.
July 30, 2003	• Court issues Scheduling Order setting December 31, 2003 as the deadline for filing motions to amend pleadings • Fact discovery begins • Wyeth serves interrogatories on Teva, seeking the basis for any non-infringement and unenforceability defenses
August 2003	• According to Teva's February 22, 2005 letter, "Wyeth has been on notice since August 2003 of Teva's efforts to develop an inequitable conduct defense and counterclaim"
August 29, 2003	• Teva answers Wyeth's interrogatories • Teva does not identify any inequitable conduct defense
October 31, 2003	• Wyeth produces its NDA o Includes all clinical trials o Identifies only two eight week (Studies 209 and 367) and one 12 week (Study 208) clinical trials • Teva stated during the May 9th Oral argument that reviewing these materials "raised a red flag"
December 5, 2003	• Teva answers Wyeth's interrogatory on infringement and does not identify "diminished incidence of nausea and emesis" as a basis for non-infringement
December 31, 2003	• Last day to amend pleadings
May 3, 2004	• Wyeth provides Teva with its claim construction
June 15, 2004	• Teva provides Wyeth with its claim construction, defining "incidence of nausea" as "level of nausea"
February 14, 2005	• Teva notifies the Court and Wyeth for the first time of its intention to raise an inequitable conduct defense

[1] Teva also waited until the last day of fact discovery to change its position on Wyeth's July 30, 2003 interrogatory seeking the identity and basis for any unenforceability defense.

February 18, 2005	• Teva changes its claim construction of "diminished incidence of nausea and emesis," deleting reference to "level of nausea" • Teva amends interrogatory answer to allege inequitable conduct • Teva amends interrogatory answer to allege a new ground of non-infringement based on its new claim construction

In a February 17, 2005 teleconference, the Court instructed Teva to explain why it could not have filed its motion earlier and subsequently ordered Teva to "submit a letter that sets forth the facts that support good cause to modify the scheduling order's deadline for filing such a motion." [Order of February 20, 2005, Steiner Ex. 4]. In response, Teva tried to justify its last minute attempt to allege inequitable conduct by claiming that certain depositions conducted in early February 2005 provided new information that was the basis for its allegations.

The Court permitted Teva to file its motion for leave, but expressly instructed Teva to "include an explanation of how the February, 2005 depositions provided newly discovered evidence that it did not possess before the February 17, 2005 telephone conference." [March 22, 2005 Order at 5 ("3/22/05 Order"), Steiner Ex. 5]. The Court further advised Teva that "if good cause is not presented, then the Court may consider whether or not Fed. R. Civ. P. 16 should bar the motion . . . ." [*Id.*]. However, in its April 1, 2005, Motion Seeking Leave to Amend it Answers, Teva failed to present any evidence uncovered at the February 2005 depositions that could justify its delay in seeking to amend its Answer. In fact, Teva failed to even discuss the criteria of Rule 16 despite the Court's warning that it could form the basis for barring its motion.

The Court gave Teva yet another opportunity to explain its delay by granting its request for an oral argument on its motion and conducted an extensive hearing on May 9, 2005. Teva again failed to adequately explain its delay because it has no explanation. The Court's detailed ruling at the May 9th hearing correctly explains why Teva failed to satisfy the "good cause" requirement of Rule 16. Moreover, the Court provided additional observations relating to

Rule 15(a) that further support the denial of Teva's motion. As explained below, Wyeth respectfully submits that the Court affirm Judge Shwartz's decision.

III. MAGISTRATE JUDGE SHWARTZ'S RULING UNDER RULE 16 IS NEITHER CLEARLY ERRONEOUS NOR CONTRARY TO LAW

A. Rule 72(a) Standard Of Review

A motion to amend pleadings is usually considered nondispositive and may be ruled on finally by a magistrate judge under 28 U.S.C. § 636(b)(1)(A) subject to Rule 72(a). *Doe v. Nevada Crossing, Inc.*, 920 F. Supp. 164, 165-66 (D. Utah 1996). Under Rule 72(a), a Magistrate Judge's order will only be set aside upon a finding by the district court that the order was clearly erroneous or contrary to law. *National Labor Relations Board v. Frazier*, 144 F.R.D. 650, 660 (D.N.J. 1992); *Haines v. Liggett Group, Inc.*, 975 F.2d 81, 92 (3d Cir. 1992). A finding is clearly erroneous when "the reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has been made." *Frazier*, 144 F.R.D. at 660.

Magistrate judges have broad discretion in resolving nondispositive matters, and the party seeking to overturn such an order bears a heavy burden. *J.G. Peta, Inc. v. Club Protection, Inc.*, No. 99-CV-616 (NPM/GJD), 2001 WL 536280, *1 (N.D.N.Y. May 18, 2001). Under this deferential standard of review, "[w]here there are two permissible views of the evidence, the factfinder's choice between them cannot be clearly erroneous." *Multi-Tech Sys., Inc. v. Hayes Microcomputer Prods., Inc.*, 800 F. Supp. 825, 854 (D. Minn. 1992) (denying motion to amend complaint to add punitive damages claim after the deadline for amending pleadings had passed).

B. Magistrate Judge Shwartz Correctly Applied The Good Cause Requirement Of Rule 16

Rule 16 explicitly provides that the deadlines in a pretrial scheduling order "shall not be modified except upon a showing of good cause and by leave of the district judge . . . . " Fed. R. Civ P. 16(b). Thus, the grant of a motion to modify a scheduling order deadline in order to

amend pleadings requires "a showing of good cause if it cannot reasonably be met despite the diligence of the party seeking the extension." Fed. R. Civ. P. 16, Advisory Committee's Notes. Absent such a showing, "[t]he careful scheme of reasonable framing and enforcement of scheduling orders for case management would thus be nullified if a party could inject amended pleadings upon a showing of less than good cause after scheduling deadlines have expired." *Harrison Beverage Co. v. Dribeck Importers, Inc.*, 133 F.R.D. 463, 469 (D.N.J. 1990).

As a tool for the enforcement of scheduling orders and Court-ordered deadlines, Rule 16 provides an "overlay" to the more lenient provisions of Rule 15. *Id.* In *Sosa v. Airprint Sys., Inc.*, 133 F.3d 1417, 1419 (11th Cir. 1998), the court held that because the motion to amend was filed after the deadline, the movant was wrong to focus on the more liberal standard of Rule 15, and "must first demonstrate good cause under Rule 16(b) before we will consider whether amendment is proper under Rule 15(a)." *See also, id.* ("If we considered only Rule 15(a) without regard to Rule 16(b), we would render scheduling orders meaningless and effectively would read Rule 16(b) and its good cause requirement out of the Federal Rules of Civil Procedure."). Thus, Rule 16 focuses on the diligence of the party seeking leave to modify the scheduling order. *Id.*; *see also*, *Gonzalez v. Comcast Corp.*, No. Civ. A 03-445-KAJ, 2004 WL 2009366 (D. Del. Aug. 25, 2004) (no good cause shown where defendant's motion was 7 months after deadline to amend pleadings and improperly focused on prejudice to non-movant rather than good cause). Indeed, when a Rule 16 deadline has passed, a court need not even reach the additional issues raised under Rule 15(a) if the "good cause" requirement of Rule 16 has not been satisfied. *Colorado Visionary Acad. v. Medtronic, Inc.*, 194 F.R.D. 684, 687 (D. Col. 2000); *accord E. Minerals & Chem. Co. v. Mahan*, 225 F.3d 330, 340 (3d Cir. 2000).

Thus, Rule 16 "'is not coterminous with the amendment standard embodied in Rule 15(a).'" *Colorado Visionary*, 194 F.R.D. at 687. To the contrary, "Rule 16(b) erects a more stringent standard, requiring some persuasive reason as to why the amendment could not have been effected within the time frame established by the court:"

> Rule 16(b)'s "good cause" standard is much different than the more lenient standard contained in Rule 15(a). Rule 16(b) does not focus on the bad faith of the movant, or the prejudice to the opposing party. Rather, it focuses on the diligence of the party seeking leave to modify the scheduling order to permit the proposed amendment. Properly construed, "good cause" means that scheduling deadlines cannot be met despite a party's diligent efforts. In other words, this court may "modify the schedule on a showing of good cause if [the deadline] cannot be met despite the diligence of the party seeking the extension." Carelessness is not compatible with a finding of diligence and offers no reason for a grant of relief.

Id. Consistent with these principles, Judge Shwartz framed the question as "whether or not Teva could have reasonably been expected to meet the December 31, 2003 deadline to file its motions to amend having–if it had applied due diligence." [5/9/05 Tr. at 87-88].

Noting that "there was sufficient information long before February 2005 for which–upon which Teva could have sought leave or at least could have come before this Court and sought an extension at that time," and that "it appears that, at least from October 2003, Teva had possession of the information upon which it now relies for its proposed amendment," (5/9/05 Tr. at 91), the Court found that Teva did not establish good cause for its proposed amendment (*id.* at 92). Consequently, the Court denied Teva's motion under Rule 16. [*Id.* at 92-93].

Judge Shwartz's application of the good cause standard under Rule 16 is certainly not contrary to law. Numerous courts have recognized the propriety of applying the good cause standard of Rule 16, instead of the more lenient provisions of Rule 15, once a deadline to amend pleadings has passed. *See Sosa,* 133 F.3d at 1419 (requiring movant to first demonstrate good cause under Rule 16(b) before the court would consider whether amendment is proper under

Rule 15(a)); *In re Milk Prods. Antitrust Litigation*, 195 F.3d 430, 437 (8th Cir. 1999) (noting that a court may properly require that good cause be shown for leave to file an amended pleading that is substantially out of time under a Rule 16 scheduling order). It was thus entirely appropriate for Judge Shwartz to deny Teva's motion under Rule 16.

Teva has failed to demonstrate that Judge Shwartz erred in applying Rule 16. Notwithstanding Judge Shwartz's admonition that "if good cause is not presented, then the Court may consider whether or not Fed. R. Civ. P. 16 should bar the motion" (Steiner Ex. 5 at 5), Teva has consistently ignored Rule 16, and continues to ignore it in its present appeal. Instead, Teva continually argues that unless Wyeth can show prejudice under Rule 15, Teva's motion to amend should be granted, as if Rule 16 did not exist. For Teva to ignore Rule 16 and rely solely on Rule 15 to argue that its motion is warranted *is* contrary to law. As such, the Court should affirm Judge Shwartz's application of Rule 16. *See Anda v. Ralston Purina, Co.*, 959 F.2d 1149, 1155 (1st Cir. 1992) (if allowance of amendment would nullify purpose of Rule 16, district court did not abuse its discretion by adhering to scheduling order and refusing to allow amendment).

C. Teva Cannot Show Clear Error In Magistrate Judge Shwartz's Ruling

Similarly, Teva cannot demonstrate clear error in Judge Shwartz's May 9th finding that Teva had in its possession in October 2003, long before February 2005, the information upon which it now relies for its proposed defense, and that it failed to exercise diligence during this over 15 month period. [5/9/05 Tr. at 89-91].

1. Teva Was Not Diligent

Teva does not dispute that by October of 2003--two months before the deadline to amend--Wyeth had produced to Teva a copy of Wyeth's May 1996 NDA, including the Final Reports of Studies 208, 209, and 367. Teva's entire inequitable conduct allegation is that those studies do not support the statement of statistical significance in the patents. But the statement in

the patents and the studies had been in Teva's possession for over 15 months before it sought to amend the pleadings. And there could be no confusion in identifying the studies referred to in the patents because there were only two completed 8-week and one completed 12-week trials in Wyeth's NDA, which was filed in May 1996–just two months after the original patent application was filed in March 1996. Therefore, the Court did not err in finding that Teva had the information on which it bases its defense since October 2003.

Teva argues that it needed to confirm the studies referred to in the patents through depositions of the inventors and Wyeth's Rule 30(b)(6) designees. [5/27/05 Br. at 7]. But Judge Shwartz specifically considered this argument, and found that Teva "has not explained why it did not bring this motion sooner and exactly what about the February 2005 deposition cemented its ability to assert its proposed amendment based on information that was not known to it before that date." [5/9/05 Tr. at 88]. Both of these findings are amply supported by the record.

As to Teva's failure to act sooner, Judge Shwartz specifically asked Teva:

> Let's go back to the fall of 2003 where, at that point in time, it's been represented without dispute there was disclosure of the patent and a disclosure of the NDA. If there was confusion about which of the studies in the NDA correspond to the statements in the patent, why wasn't a deposition done then? Why wait until five months later, six months later to issue a deposition notice if this became–if this to you was unclear. Why wait?

[5/9/05 Tr. at 47]. Tellingly, in response, Teva's counsel surmised that "we made a determination at the time that it was not--we weren't going to go through each statement at that time and try and figure out all of the details," (*id.* at 48), notwithstanding the fact that Teva's counsel represented to the Court that when Teva reviewed Wyeth's October 2003 NDA production, "it raised a red flag for us." [*Id.* at 6].

Further, because Teva also had the underlying clinical data for these studies by October 2003, it had all of the information regarding the clinical trials necessary to determine for itself

the basis for the "statistically significant improvement" statement in the patents. Teva certainly did not need to wait more than a year after the December 31, 2003 deadline to amend pleadings to confirm the clinical study numbers that it already had from Wyeth's NDA. *Samick Music Corp. v. Del. Music Indus., Inc.*, 1992 WL 39052 at *7 (D. Del. Feb. 12, 1992) (motion to amend the pleadings denied where facts necessary to bring the counterclaims were long known and recent "confirmation" was superfluous). And, as the Court aptly pointed out, Teva "could have conducted its own analysis of the clinical information." [5/9/05 Tr. at 90]. Teva has not challenged this finding as clearly erroneous.

Teva also argues, as it did before Judge Shwartz, that it "deferred amendment of its answers until it had developed the factual underpinnings required to assert the inequitable conduct defense." [5/27/05 Br. at 2]. Teva contends it was required to wait until Wyeth's document production was substantially complete in October 2004, before it could proceed with depositions of the four inventors of the patents and then, only after it was allegedly determined that the inventors had no knowledge of the disclosed clinical trials, two Rule 30(b)(6) depositions on the subject of the invention of the patents and Wyeth's clinical trials. [5/27/05 Br. at 2-3].[2] But Teva had all of the documents it now relies upon by October of 2003. Teva knew Wyeth's NDA contained all the clinical studies completed at the time of the patent application

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[2] Teva argues that "[n]one of the four inventors had any knowledge about the basis" for the statements in the patents pertaining to nausea and vomiting. [5/27/05 Br. at 4]. In fact, inventor Deborah Sherman testified that it was indeed her belief from working at Wyeth as part of the research-wide project team for Effexor® XR that Effexor® XR had a better side effect profile with regard to nausea than the immediate release formulation. [Sherman Tr. 291:1-19, Steiner Ex. 6]. Furthermore, Teva's counsel never asked inventor John Lamer whether he knew the *basis* for the patent statement at issue. At most, Mr. Lamer was asked what role he played in determining that the use of Effexor® XR resulted in reduced nausea and emesis. [Lamer Tr. at 230:2-232:2, 281:3-282:3, Steiner Ex. 7].

filing and if there were any question, Teva could have verified the facts in 2003 by interrogatory or deposition.

Similarly, Teva did not need to take the depositions of the inventors in order to determine which clinical trials underlie the statement of statistical significance in the patents. More importantly, however, Teva has not cited, nor can it cite, any testimony from the inventors to support any assertion of an intent to mislead the Patent and Trademark Office (PTO). And Teva relies upon nothing in the inventor depositions to support its theory of inequitable conduct.

Teva mischaracterizes Judge Shwartz's ruling regarding the order of the Rule 30(b)(6) depositions. To be sure, Wyeth objected to the breadth of Teva's June 2004 Rule 30(b)(6) notice, and at the August 5, 2004, hearing Judge Shwartz agreed that the topics noticed by Teva were too broad. [8/05/04 Hearing Tr. at 62, Steiner Ex. 8]. On August 9, 2005, Judge Shwartz ruled that Wyeth was to produce Rule 30(b)(6) witnesses to testify about, *inter alia*, clinical trials that "Teva specifically identifies." [8/09/04 Order at 2, Steiner Ex. 9]. Judge Shwartz imposed no time or order restrictions on these depositions, and had Teva been truly diligent as it now argues, it would have re-noticed these narrowed Rule 30(b)(6) depositions promptly after the August 5th hearing. Instead, Teva delayed another three months, to November 2004, before identifying the clinical trials that were to be the subject of the re-noticed narrower Rule 30(b)(6) deposition, yet attempts to justify its delay by arguing that it was acting "[p]ursuant to the procedure agreed upon at the August 5, 2004 hearing before Judge Shwartz." [5/27/05 Br. at 4]. Significantly, it was not until December 2, 2004 that Teva specifically identified the statement of statistical significance in the patents as a Rule 30(b)(6) topic. [12/2/04 Notice of Deposition at 4, Steiner Ex. 10]. Teva, however, has never explained why it could not have served such a narrow notice far earlier in the litigation. Accordingly, in her May 9th ruling, Judge Shwartz stated:

> In looking at the FDA new drug application, there is specific reference to three completed studies in May of 1996 that span exactly the same duration. If there was a question as to whether or not the three studies in the NDA were the same three studies referred to in the patent, steps could have been taken long before February 2005 to determine that fact and if that fact had been nailed down, that's the only new fact that the parties have indicated were not–sorry–that Teva has indicated was not known to it at the time.

[5/9/05 Tr. at 89]. Thus, Judge Shwartz's findings are not clearly erroneous.

2. The February 2005 Depositions Clarified Nothing That Teva Did Not Already Know or Should Have Acted Upon Prior to the December 2003 Deadline

Teva states, as it did before Judge Shwartz, that during their February 2005 depositions, Dr. Mangano and Mr. Alaburda finally identified Studies 208, 209 and 367 as the three clinical studies referred to in the patents specification.[3] [5/27/05 Br. at 7]. But Teva did not need to wait for over 15 months–from October 2003 until February 2005–to find out what it already knew or should have known; that the 208, 209 and 367 studies were the three clinical studies referred to in the patents statement at issue.

Dr. Mangano and Mr. Alaburda both further testified that Study 208, by itself, established significant improvement in vomiting rates between Effexor® XR and the immediate release Effexor®, and that pooled data from Studies 208, 209, and 367 demonstrate statistically significant improvements in both nausea and vomiting rates for Effexor® XR relative to Effexor®. The witnesses also testified as to additional analyses in the studies that showed improvements for Effexor® XR as compared to Effexor®. For example, in one such analysis, both deponents pointed to the Integrated Safety Summary ("ISS"), a part of Wyeth's May 16, 1996 Effexor® XR NDA. The ISS presents a table of pooled data from these three placebo-

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[3] Teva cites *Enzo Life Sciences*, *Go Medical*, and *Douglas Press* at p. 11 of its brief to argue that it required the February 2005 depositions to confirm the 3 specific clinical studies referred to in the patents. In those cases, new facts warranted the granting of leave. Here, as Judge Shwartz found, Teva did not need to wait until the end of fact discovery to verify what it already knew.

controlled clinical trials for certain adverse events in these studies, including nausea and vomiting. Juxtaposed on the same table, the ISS presents corresponding pooled data for Wyeth's placebo-controlled clinical trials on the immediate release formulation. Simple known mathematical calculations show statistically significant differences between the nausea and vomiting rates in the two pools. Wyeth produced the ISS to Teva on October 31, 2003.

Teva argues that at their depositions, Dr. Mangano and Mr. Alaburda presented "brand new, never-before-seen, elaborate calculations and permutations of the original clinical study data purportedly showing a diminished incidence of nausea and emesis." [5/27/05 Br. at 8, emphasis added]. But Teva had the same "original clinical study data" in October 2003 when Wyeth produced its NDA, and Teva could have performed its own statistical calculations on it at that time. Furthermore, under Teva's theory, any statistically significant difference obtained by comparisons of pooled data is purportedly irrelevant. In other words, Teva is simply arguing that Wyeth cannot rely on pooling. [4/1/05 Br. at 1, (alleging Wyeth misrepresented its nausea and emesis results to the PTO because "the specification does not state that the conclusions are based upon a 'pooled' analysis.")].

To support its new inequitable conduct argument, Teva interprets (but in reality seeks to rewrite) the patent statement as referring to statistically significant improvements shown independently in *each* of the two eight-week and one twelve-week studies. But that is not what the patent says:

> Venlafaxine ER showed a statistically significant improvement over conventional venlafaxine hydrochloride tablets in two eight-week and one 12 week clinical studies.

['171 patent at col. 2, ll. 52-55]. Wyeth disagrees with Teva's position that the above statement cannot refer to all three studies taken collectively, as did Judge Shwartz. [5/9/05 Tr. at 100-101]. On its face, the statement is not written as Teva suggests, and there is no basis for imposing

Teva's additional, artificial requirement. Moreover, nothing in the February 2005 depositions supports such a strained reading. But at any rate, under Teva's interpretation of the above quoted passage, all testimony regarding pooling is purportedly irrelevant, and could not have been a predicate to Teva's inequitable conduct defense. Teva's defense simply does not depend on testimony from the February 2005 depositions regarding statistical analyses of pooled data.

Moreover, the concept of pooling adverse event data from clinical studies is well known, as evidenced by Wyeth's ISS, Wyeth's labels for both Effexor® and Effexor® XR, and Teva's own proposed label for its extended release venlafaxine capsules, all of which were known to Teva by October 2003. Indeed, the Physician's Desk Reference ("PDR") for Teva's own Copaxone® product relies on pooled data for the same purpose, and compares the percentage of patients experiencing adverse events during treatment with its Copaxone® product versus that of placebo in pooled studies. [PDR at 3221-3225 (59th ed. 2005), Steiner Ex. 11]. Consequently, it cannot come as a surprise to Teva that Wyeth relies on, among other evidence, a comparison of pooled data to support the patents' statement at issue. And learning that such additional support exists hardly justifies Teva's failure to raise its inequitable conduct allegation earlier.

Finally, Teva also notes that it took the deposition of Dr. Richard Rudolph in February 2005 [5/27/05 Br. at 4], but points to no newly discovered evidence without which Teva could not have raised its allegation earlier. That is not surprising as Dr. Rudolph's testimony supports the improved nausea and emesis profile of Effexor® XR:

> Q. (By Teva's Counsel) I know you said before that you had come to the conclusion, based on your work with Venlafaxine ER and Venlafaxine IR, that nausea and vomiting were significantly less of a problem with the extended release version than the immediate release version; right?
>
> A. I–I said based on the work that I did with–with Effexor, both–both formulations, that it was my strong conclusion that nausea and vomiting

> were much less of a–a barrier or problem for patients taking the extended release than it was for patients taking the immediate release.

[Rudolph Tr. at 36, Steiner Ex. 12].

Judge Shwartz carefully considered Teva's argument that the February 2005 depositions revealed new evidence that Teva needed before it could assert its inequitable conduct defense. [*E.g.* 5/9/05 Tr. at 78-79, 82-83]. Judge Shwartz found, however:

> I note today, at oral argument, what was learned for the first time was really a confirmation that the studies referred to in the NDA were the studies that were referred to in the patent application and that's what became clear from those depositions.

[5/9/05 Tr. at 79; *see also id.* at 51]. Since Teva had the NDA since October 2003, Judge Shwartz "does not find that waiting until February 2005 to solidify that fact was a diligent use of one's time." [5/9/05 Tr. at 89-90]. Judge Shwartz further noted that Teva had the underlying studies as early as fall of 2003, and that Teva "could have conducted its own analysis of the clinical information." [*Id.* at 90]. And finally, the Court stated at pp. 90-91:

> To the extent Teva asserts the patent application misrepresents data from the three studies because Wyeth did not explicitly state the data was pooled and that pooling was the only way they could have established statistical significance or that Wyeth's statements were based on studies not specifically disclosed to the PTO, Teva had within its possession the NDA filed within 60 days of the patent application and could have compared the assertions to the PTO with those made to the FDA.

The February depositions provided Teva with nothing they did not already know, and as Judge Shwartz ruled, there was simply no excuse for Teva's delay in seeking to amend its Answers.[4] As Teva cannot show any error in this rationale, Judge Shwartz's ruling should be affirmed.

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[4] At pp. 12-13 of Teva's Brief, a number of Rule 15 cases (*Adams, Kiser, In re K-Dur, Bouton, Miller, Boileau,* and *Leased Optical Departments-Montgomery Ward*) are cited for the proposition that denial of leave cannot be based on the passage of time alone -- undue delay or prejudice must be shown. But Judge Shwartz based her ruling of undue delay under Rule 16 on Teva's lack of diligence, not the mere passage of time. Further, Judge Shwartz ruled that Wyeth would have been prejudiced if Teva's amendment were allowed. These cases are inapposite.

IV. MAGISTRATE JUDGE SHWARTZ'S OBSERVATIONS UNDER RULE 15 PROVIDE FURTHER SUPPORT FOR HER MAY 9th RULING

Although Judge Shwartz denied Teva's motion under Rule 16, she made observations concerning the propriety of also denying Teva's motion under Rule 15. Those observations, which address both prejudice and futility, were neither contrary to law nor clearly erroneous.

A. Magistrate Judge Shwartz Was Correct That Wyeth Would Be Prejudiced By Teva's Amendment

Leave to amend under Rule 15 may be denied if there is a finding of, *inter alia*, undue delay, undue prejudice to the opposing party, or futility. *See Foman v. Davis*, 371 U.S. 178, 182 (1962). As discussed above, Judge Shwartz's conclusions regarding undue delay are neither clearly erroneous nor contrary to law. As discussed below, the Court's additional observations concerning prejudice and futility are also neither clearly erroneous nor contrary to law.

1. Wyeth Could Not Have Reasonably Anticipated That on the Last Day of Fact Discovery, Teva Would Suddenly Dispute the Differences in Nausea and Vomiting Between the ER and IR Formulations

Teva first argues that there can be no prejudice because Wyeth anticipated that Teva would assert its inequitable conduct defense. [5/27/05 Br. at 15]. However, Teva fails to explain why Wyeth should have anticipated that Teva would assert its inequitable conduct defense when throughout this litigation--right up to the very last day of fact discovery it was never raised.

Until the last day of fact discovery, Teva never disputed that there were differences in the side effect profiles between the immediate release and extended release venlafaxine formulations. Prior to this lawsuit, Teva filed its Abbreviated New Drug Application ("ANDA") on its extended release venlafaxine formulation with the FDA. Teva was required by law to provide Wyeth, as owner of the patents and holder of the NDA, with notice that Teva's ANDA

contained a patent certification under 21 U.S.C. § 355(j)(2)(a)(vii)(IV), commonly referred to as a "Paragraph IV" certification. Teva's Paragraph IV certification had to contain the basis for Teva's assertion that its generic product does not infringe Wyeth's patent claims, and/or that the patent claims are invalid. Notably, Teva's Paragraph IV certification contained no basis of non-infringement of the asserted patent claims, let alone a non-infringement position based on any assertion that Teva's extended release product did not have "diminished incidences of nausea and emesis" as compared to immediate release formulations.

On July 30, 2003, the first day of fact discovery, Wyeth served an interrogatory on Teva which asked Teva if it contended "that any of the patents-in-suit is unenforceable," and to "describe in detail all factual and legal bases" for any such contention. Notably, Teva's February 22, 2005 letter to Judge Shwartz stated that Wyeth was on notice since August 2003 that Teva was developing an inequitable conduct defense. Yet Teva's August 29, 2003 response to the interrogatory never disputed the statement in the patents regarding the differences in side effects between the immediate release and extended release formulations. Rather, Teva's response was simply that the interrogatory was premature and that Teva would supplement its response once it received Wyeth's claim construction and infringement analysis. [Teva Resp. to Interrog. No. 5 at 12, Steiner Ex. 13]. Although Wyeth gave Teva its detailed infringement analysis in October 2003 [Steiner Ex. 22] and its claim construction in May 2004 [Steiner Ex. 23], Teva never supplemented the interrogatory until February 18, 2005–the last day of fact discovery. Wyeth also served an interrogatory requesting Teva's factual and legal contentions regarding non-infringement. And while Teva raised non-infringement contentions for the asserted claims, Teva never alleged non-infringement based on the claimed "diminished incidences of nausea and emesis" until it also supplemented that interrogatory on February 18, 2005.

And it is no surprise that Teva never disputed the difference in nausea and vomiting between the extended and immediate release formulations of venlafaxine. During discovery, Wyeth uncovered evidence that, in addition to Teva's ANDA for extended release venlafaxine, Teva also had filed an ANDA for an immediate release ("IR") venlafaxine formulation. Interestingly, it was also discovered that in its ANDA for IR venlafaxine, Teva submitted *in vivo* testing on only its lowest strength IR dosage form (25 mg). Teva submitted no *in vivo* testing on any of its higher IR dosage strengths (37.5 mg, 50 mg, 75 mg, and 100 mg) because the Canadian company Anapharm, a Contract Research Organization that conducts human clinical trials for Teva, was unable to complete trials on a 75 mg dosage strength due to excessive patient dropouts from nausea and vomiting. In a letter to Teva, Anapharm states:

> In 2002, Anapharm had started a 75mg Venlafaxine IR study. This study initially included 24 healthy males or females subjects. Twelve (12) subjects had to be withdrawn because they experienced vomiting within 4 hours post-dose. . . . The sponsor decided to stop the study after period 1. Eighty-six (86) adverse events were recorded post-dose (mainly nausea, dizziness, hot flashes, sleepiness). In parallel, Anapharm also started a 37.5mg IR fasting study with 48 male. After period 1, 12 subjects had to be withdrawn due to vomiting within 4 hours post-dose. In total, 17 subjects experienced vomiting (30% of the volunteers) within 4 hours post-dose.
>
> * * *
>
> ... We consider that giving more than 25mg under fasting conditions to healthy volunteers would be harmful to their health, safety and well-being. This drug has a high potential of adverse effects especially affecting the CNS (dizziness, sleepiness and anxiety) and gastro-intestinal tract (nausea, diarrhea and vomiting).
>
> Moreover, we received a written confirmation (enclosed) from our Ethics Committee (EC) stating that they would not approve a study giving more than 25 mg of Venlafaxine IR under fasting conditions and 37.5mg of Venlafaxine IR under fed conditions to healthy subjects. They also stated that it would be unethical to begin studies with higher doses, e.g. 100mg.

[Elkoshi Dep. Ex. 20, Steiner Ex. 14]. Not being able to conduct *in vivo* testing on the dosage strengths above 25 mg of the IR product, Teva submitted a request for waiver to the FDA in its

immediate release ANDA. [Elkoshi Dep. Ex. 16, Steiner Ex. 15]. As support for its waiver, Teva submitted the Anapharm letter quoted above. [Elkoshi 20 at Teva 039079, Steiner Ex. 14].

In sharp contrast to Anapharm's experience with the IR dosage form of venlafaxine, Teva's studies with even the highest dosage strength (150 mg) of its extended release venlafaxine capsules did not require premature termination due to adverse events. [*Compare* Elkoshi Tr. at 153:5-154:7, 156:15-19 *with* 121:14-21, 123:15-19, Steiner Ex. 16]. These facts from Teva's own documents and witnesses directly refute the inequitable conduct allegations Teva now seeks to make.

Consequently, given that Teva did not amend its pleadings in December 2003 to allege inequitable conduct, which it was required to do if it were going to assert such a defense, never argued non-infringement based on the claim term "diminished incidences of nausea and emesis," never asserted an inequitable conduct defense in response to a specific July 2003 interrogatory, and produced documents showing that Teva knew that the extended release formulation had less nausea and vomiting as compared to the immediate release formulation, it is incongruous for Teva to now argue that Wyeth should have anticipated its 180° change in position. That Wyeth took limited discovery of Teva to show that Teva realized the benefits of Wyeth's patented invention (5/27/05 Br. at 15), or that Wyeth prepared their Rule 30(b)(6) witnesses so they could testify on topics set forth in Rule 30(b)(6) notices (*id.* at 15), or that Wyeth submitted to the FDA minor corrections to a clinical trial report (*id.* at 15-16), does not change this conclusion.

2. Magistrate Judge Shwartz was Correct that Teva's Last Minute Change in Theory Deprived Wyeth of the Opportunity to Seek Further Discovery of Teva's Knowledge of the Differences in Nausea and Vomiting Between the ER and IR Formulations

At pages 13-14 of its brief, Teva argues that to show prejudice, the party opposing the amendment of a pleading must show that it was unfairly disadvantaged or "deprived of an

opportunity to present facts or evidence which it would have offered had the amendment been timely." [5/27/05 Br. at 13-14, emphasis added]. As the record shows, Wyeth provided Judge Shwartz with the examples of discovery it would have pursued had Teva disputed earlier that there were differences between the side effects of the IR and ER formulations.

Specifically, at the time Wyeth discovered Teva's experiences with its immediate release venlafaxine studies, there was no dispute with Teva as to the differences in nausea and vomiting as between the extended release and immediate release venlafaxine formulations. As there was no dispute, Wyeth took only limited discovery and opted to forego certain additional discovery concerning the information Teva submitted to the FDA from Anapharm. Because Wyeth would have taken very seriously any allegation that it committed inequitable conduct, if Teva had asserted its inequitable conduct allegation in a timely manner, Wyeth would have expanded its discovery efforts to marshal additional evidence on Teva's failed effort to test its own immediate release dosage form. For example, Wyeth would have sought additional discovery from Anapharm in Canada. In addition, Wyeth would have raised with Judge Shwartz Teva's refusal to produce its internal correspondence relating to nausea and vomiting experienced with the immediate release dosage form of venlafaxine. [*See* 9/24/04 ltr. from Wyeth to Teva, Steiner Ex. 17; October 7, 2004 ltr. from Teva to Wyeth, Steiner Ex. 18].[5] And depending on the documents it would have received, Wyeth's list of witnesses to depose would likely have changed. Moreover, as Teva now contests the pooling of clinical data in connection with its inequitable conduct charge, Wyeth would have sought discovery on Teva's use of pooled data.

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[5] During discovery, Wyeth requested from Teva all e-mails and internal correspondence between Dr. Elkoshi and others (including Anapharm) relating to bioequivalence testing on Teva's IR dosage form that Dr. Elkoshi referenced in his deposition. [10/19/04 ltr. from Wyeth to Teva, Steiner Ex. 19]. Teva refused to produce these materials. [10/22/04 ltr. from Teva to Wyeth, Steiner Ex. 20].

During the May 9th hearing, Judge Shwartz made the following observation:

> At this stage of the proceedings where you're in the midst of expert discovery and fact discovery closed in February 2005, to allow this amendment on Rule 15 grounds would have caused undue prejudice to Wyeth. Wyeth had elected not to pursue certain discovery based upon certain agreements between counsel on the IR versus ER issues. It did not pursue allegations–strike that.
>
> Did not pursue investigating anything connected with Anapharm. There has already been a representation by Teva that it really doesn't matter what Wyeth knew–sorry–what Teva knew about the product since the focus about intentional misrepresentation really focused on what Wyeth knew, when it knew it, and what it did or did not tell the patent office. But the Court must note that this is an equitable remedy and surely Wyeth would want to be able to introduce whether or not Teva had similar perspectives about the side effects or the decrease in side effects in the formulations when administered to the patients and then they would be able to argue whether or not the representation in the patent, even if proved to be not accurate, warrants the type of relief that are being --that's being sought by way of unenforceability or declaration of invalidity.
>
> So I would find that that type of discovery would have been warranted, at least on some level and now that could not take place. So for that additional reason, the Court notes that there would be prejudice had the amendment be permitted at this late time.

[5/9/05 Tr. at 94-95]. For the reasons set forth above, Judge Shwartz was correct that Wyeth would be prejudiced by Teva's last minute amendment to add an inequitable conduct defense.[6]

B. Magistrate Judge Shwartz Was Also Correct That Allowing Teva To Amend Would Have Been Futile

Judge Shwartz also correctly observed that it appeared that Teva's inequitable conduct allegation may not have withstood a Rule 12(b)(6) motion to dismiss and was therefore futile. [5/9/05 Tr. at 101:9-11]. To demonstrate inequitable conduct, Teva must meet the heavy burden of proving by clear and convincing evidence both (1) an affirmative misrepresentation or

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[6] Teva cites two more Rule 15 cases, *Miller* and *Fingermates*, for the proposition that unjustified delay alone is not grounds to deny a motion to amend, but that unfair prejudice must be shown. [5/27/05 Br. at 16]. Once again, Judge Shwartz found that granting Teva's motion would prejudice Wyeth by denying it discovery on Teva's knowledge and experience regarding the differences between the ER and IR venlafaxine formulations. As Teva has not shown this observation to be clearly erroneous, these cases are unavailing.

omission of a material fact to the PTO, and (2) the specific intent to deceive the PTO. *Alza Corp. v. Mylan Labs., Inc.*, 391 F.3d 1365, 1373 (Fed. Cir. 2004). As set forth below, because Teva has not established either an affirmative misrepresentation to the PTO by Wyeth, or the specific intent to deceive the PTO, Judge Shwartz's observation was correct that Teva's proposed amendment could not survive a motion to dismiss and is therefore futile. *Warner-Lambert Co. v. Teva Pharms. USA*, 289 F. Supp. 2d 515, 544-45 (D.N.J. 2003) (denying Teva's motion for leave to add inequitable conduct defense as futile).

1. The Statement in the Patents is True and So Teva Cannot Demonstrate a Misrepresentation

The crux of Teva's inequitable conduct argument is that the statement in the patents that "Venlafaxine ER showed a statistically significant improvement over conventional venlafaxine hydrochloride tablets in two eight-week and one 12 week clinical studies" was a misrepresentation to the PTO. Teva interprets the statement in the patents regarding "two eight-week and one 12 week clinical studies" as meaning that *each* of those three studies must independently demonstrate a statistically significant improvement between the ER and IR formulations, and that the "improvement" must be in the "incidence" of both nausea and vomiting, as Teva defines "incidence." According to Teva, because Wyeth must "pool" its clinical data, but did not expressly state the data was pooled, it misrepresented the clinical trials before the PTO. Once again, the same argument was properly rejected by Judge Shwartz.

The plain language of the patents passage in question does not state or suggest that each of the three clinical trials independently supports the statistically significant improvement of the extended release formulation over the immediate release formulation–a point that Judge Shwartz noted when Teva raised the issue before her:

> But, you see, I think an interesting thing you just said is the way you phrased "we have three statistically significant studies." That is not exactly what was said to the patent examiner. It was written in a slightly different way and reading all these patent cases, it seems that everybody's a linguist in this area and that people are very careful about how they put things and the way you say it, whether it's in a passive voice, an active voice, whether you use a descriptor or you don't all seems to be significant and couldn't a reasonable examiner have concluded that together the three studies would have led to the same conclusion, which is the statistical significance in the reduction in nausea and emesis?

[5/9/05 Tr. at 11]. There is no dispute that Wyeth conducted two eight-week and one 12 week clinical studies before the March 1996 filing of the original patent application. Further, there is no dispute that if the data from the 208, 209, and 367 studies, which data was in existence prior to the filing date of Wyeth's patents, are pooled, the data shows statistically significant improvements in the "incidence" of both nausea and vomiting, even using Teva's incorrect narrow definition of "incidence."[7] There is also no dispute that Study 208, by itself, shows statistically significant improvements in both vomiting and efficacy between the extended release and immediate release formulations. Indeed, Teva does not even challenge the fact that there is an improvement in vomiting. And the fact that support for the statement in the patents exists, in part, from a pooled data analysis is not a misrepresentation and, therefore, cannot be material to patentability as Judge Shwartz observed at the May 9th hearing:

> Even under Teva's interpretation which is a different representation of what the patent actually states, the statement could still be accurate. The statement does not say the isolated results of each study showed an improvement in the incidence of nausea and emesis in the venlafaxine ER versus IR. They name the three studies taken together, it's been represented, support the statement's conclusion and is not a misrepresentation. Therefore, the Court is not sure that a reasonable examiner would find the lack of information to have been material.

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[7] Teva questions the propriety of pooling Study 367 with Studies 208 and 209. [5/27/05 Br. at 19]. But the FDA permitted Wyeth to pool the adverse events data for Study 367 in the label for Effexor® XR, and Teva has used the same pooled data in its label as well. [Erickson 9 at 420, Steiner Ex. 21].

[5/9/05 Tr. at 100-101]. Thus, as the statement in the patents is fully supported by data (including some pooled data) from Studies 208, 209 and 367, which data indisputably existed prior to the filing of the patent, the statement is true, and cannot be a material misrepresentation to the PTO.

2. Teva's Proposed Amended Answer Contains No Evidence of Any Intent to Deceive the PTO

Another gaping hole in Teva's inequitable conduct allegation provides additional support for Judge Shwartz's observation on futility. Teva has provided no evidence of any intent on the part of anyone involved with the prosecution of the patents-in-suit to deceive the PTO.[8] In fact, Teva's brief is totally silent on the issue of intent to deceive.

Interestingly, Teva stated at the May 9th hearing that the three clinical studies in Wyeth's NDA "raised a red flag" for them, but that it "does not take us through the intent requirement and other issues that are part of demonstrating inequitable conduct." [5/9/05 Tr. at 6]. Yet even after having a year of additional discovery, Teva still has no evidence of deceptive intent, and thus its inequitable conduct defense fails for this additional reason.

V. CONCLUSION

Teva had ample opportunity to demonstrate to Judge Shwartz good cause under Rule 16 for adjusting the Scheduling Order to permit Teva to amend its Answers. And Judge Shwartz

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[8] Teva cites a number of cases for the proposition that in a futility analysis, the motion to dismiss standard of Rule 12(b)(6) applies, and that the court must accept as true the allegations in Teva's proposed affirmative defenses and construe those allegations in the light most favorable to Teva. [5/27/05 Br. at 17]. However, as the 3rd Circuit has noted, even under that standard, a court need not accept as true "unsupported conclusions and unwarranted inferences." *Doug Grant, Inc. v. Greate Bay Casino Corp.*, 232 F.3d 173, 183-84 (3d Cir. 2000). Moreover, in both its February 22, 2005 proposed Amended Answers and its February 18, 2005 Supplemental Responses to Wyeth's Interrogatories, Teva merely states Wyeth acted to deceive based upon "information and belief." "Generally, allegations based on information and belief do not satisfy Rule 9(b)." *HCB Contractors v. Rouse & Assocs., Inc.*, 1992 WL 176142, *5 (E.D. Pa. July 13, 1992).

fully considered the arguments and evidence that both Teva and Wyeth twice presented, and aired at the May 9th hearing. Teva has not shown Judge Shwartz's ruling to be clearly erroneous. Instead, Teva's appeal merely rehashes the same arguments it made before Judge Shwartz in the hopes of a *de novo* review. That approach was rejected in *Pino v. Prudential Ins. Co.*, 689 F. Supp. 1358, 1361 (E.D. Pa. 1988) ("Consistent with the rule and its purpose, however, the Court does not consider *de novo* the arguments of counsel raised before the Magistrate and rejected by him. . . ."). Teva was not diligent in pursuing its defense. Judge Shwartz recognized Teva's undue delay and ruled accordingly. The Court's ruling is neither clearly erroneous nor contrary to law, and the Court's additional observations on prejudice and futility under Rule 15 are equally correct. Judge Shwartz's Order of May 13th should be affirmed.

Respectfully submitted,

Dated: June 13, 2005

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EXHIBIT 10

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Phone No.:	415-772-6964	**# Pages (incl. this):**	3
Subject:	Wyeth v. Impax	**Date:**	August 29, 2006
		Our File No.:	

Confirmation Copy to Follow: NO

Message:

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August 29, 2006

Samuel F. Ernst, Esq.
Heller Ehrman LLP
333 Bush Street
San Francisco, CA 94104-2828

Wyeth v. Impax Laboratories, Inc., Civil Action No.: 06-222 (D. Del.)

Dear Samuel:

I write in response to your letter of yesterday and in partial response to your letter of August 21, 2006. Despite your insistence that your six-page letter of August 21st provides a "point-by-point response" to each of the issues raised in my August 3rd and August 4th letters to Jessica Wolff, as further discussed below, your letter does *not* provide substantive responses to at least the following points that were raised.

My August 4th letter at pages 1-2 provides a detailed explanation on a document request by document request basis of why Impax's objections are unacceptable. Your letter simply does not respond to those portions of my letter. In addition, please represent whether Impax will produce to Wyeth documents from its files concerning (1) the development of the product that is the subject of ANDA 78-057, (2) Impax's consideration of alternate extended release venlafaxine formulations prior to the filing of ANDA 78-057, (3) Impax's consideration of development of a generic immediate release venlafaxine formulations prior to the filing of ANDA 78-057, (4) comparisons between immediate release venlafaxine and extended release venlafaxine, (5) nausea and/or vomiting in humans associated with immediate release venlafaxine, and (6) all documents concerning Effexor® XR.

Moreover, with the exception of the 3rd complete paragraph on page 3 of my August 4th letter, your letter provides no response whatsoever to pages 3-5 of that letter which identifies, in detail, concerns about both Impax General Objections 9-10 and 12 as well as Impax's myriad, specific objections to identified document requests.

Our letter of August 3rd specifically requests that Impax inform Wyeth whether there are any documents or information that Impax is withholding based on its numerous objections of breadth, ambiguity, burden, or relevance, i.e. General Objections Nos. 9-10 and 12. Impax has not responded to this request.

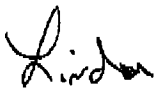
Please provide a substantive, point by point response to each portion of my letters identified above immediately. If you remain "perplexed" by my comment that your letter did not "substantively respond," please feel free to call me.

We decline to accept your suggestion to adopt a schedule according to the local rules of the Northern District of California because it circumvents the case management schedule set by the Court in this case. This case is in Delaware, not the Northern District of California. Your proposal unilaterally accelerates only the time for Wyeth to provide contentions, but leaves Impax's time unchanged. The Court has set October 10, 2006 as the date for the mutual exchange of contentions. We see no need for modification of Judge Farnan's schedule and believe that the Scheduling Order reflects the Court's views as to how the case should be managed.

We are still considering the remaining portions of your August 21st letter as well as your draft protective order and the subsequent modifications you made to that order last week. We will respond to those outstanding issues in the near future. We do not agree to the terms of the protective order you have proposed and definitely do have changes we would like to make to that draft protective order. We plan to provide you with a revised version of that protective order later this week.

Finally, to date Impax has only produced about 4500 pages of Impax's ANDA to Wyeth. Please advise us by the end of this week when we can expect the remainder of Impax's document production.

Sincerely,



Linda A. Wadler

LAW/AMM/hkr

cc: Mary B. Matterer, Esq.
Richard K. Herrmann, Esq.

CERTIFICATE OF SERVICE

I hereby certify that on the 31st day of August, 2006, I electronically filed the foregoing document, **REPLY DECLARATION OF MARY B. MATTERER IN SUPPORT OF IMPAX'S MOTION TO MODIFY SCHEDULING ORDER** with the Clerk of the Court using CM/ECF which will send notification of such filing to the following:

Jack B. Blumenfeld
Karen Jacobs Louden
Morris Nichols Arsht & Tunnell
1201 N. Market Street
Wilmington, DE 19801

Additionally, I hereby certify that on the 31st day of August, 2006, the foregoing document was served as indicated on the following:

VIA EMAIL AND HAND DELIVERY
Jack B. Blumenfeld
Karen Jacobs Louden
Morris Nichols Arsht & Tunnell
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